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Inspection in action – an evaluation of hospital inspections in Wales

Anne Christine Hanser

A thesis submitted for the degree of Professional Doctorate in
Health

University of Bath
Department for Health

March 2018

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Signed on behalf of the Faculty of Humanities & Social Sciences

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Abstract

This thesis investigated healthcare regulation practice in Wales with the aim to evaluate the strengths and weaknesses of hospital inspection regimes implemented by the Healthcare Inspectorate Wales (HIW). Applying Pawson and Tilley's (1997) realist theory-driven programme evaluation, the study interviewed 46 representatives from eight NHS organisations, five independent sector organisations and HIW.

HIW draws on various mechanisms to direct, detect and enforce compliance with standards. The research found that, while some elements of HIW's inspection regimes such as self-assessments seemingly eroded over time, others have contributed to regulatory effectiveness. Engaging healthcare managers in the standard development process has created common understanding and ownership. Professional independence and clinically-competent reviewers, who scrutinise healthcare provision, validate findings and give informed feedback, have added credibility to hospital inspections. Hospital managers generally appreciated external reviews as a 'reality check' or lever for change. Commitment to quality and the fear of exposure have motivated compliant behaviour amongst hospital managers.

Differences exist in the regulation between NHS and independent hospitals in Wales. Managers seem to find it easier to comply with or exceed healthcare standards in small, specialised hospitals than in large NHS bodies with many hierarchical levels. Further, HIW inspections have effected positive change in both NHS and independent hospitals. However, there were examples of repeated negative inspection results in some NHS hospitals. This suggests that HIW's impact on improvements in the NHS has been limited.

The findings suggest that HIW's inspection regimes can be improved by regularly reviewing inspection methods and tools, systematically monitoring improvement actions and carefully selecting reviewers with matching clinical skills. The study did not find a standard prescription for an ideal inspection regime. Conversely, regulatory effectiveness requires the inspectorate to strike the right balance between different options and for inspectors to use their professional judgement in the specific context.

List of abbreviations

BCUHB	Betsi Cadwaladr University Health Board
CHAI	Commission for Healthcare Audit and Inspection
CHI	Commission for Health Improvement
CQC	Care Quality Commission
DECI	Dignity and Essential Care Inspection
HIW	Healthcare Inspectorate Wales
LHB	Local Health Board
NHS	National Health Service
NISCHR PCU	National Institute for Social Care and Health Research Permissions Co-ordinating Unit
UK	United Kingdom

Glossary

Acute hospital	A hospital that provides medical treatment for illness, other than a mental disorder or palliative care.
Compliance	The act of meeting the requirements of accepted practices, prescribed rules, regulation, legislation or standards. Compliance is typically assessed and confirmed by a third party, which can be an independent or governmental body.
Detection	Actions that are 'directed towards individual organizations, e.g. inspecting an organization's performance in a particular area in relation to standard regulatory requirements' (Hovlid, Høifødt, Smedbråten, & Braut, 2015, p. 2).
Direction	Actions that are 'taken at a system level aiming to affect all the regulated organizations, e.g. developing health-care legislation and national guidelines for delivery of care' (Hovlid et al., 2015, p. 2).
Effectiveness	The extent to which an organisation, programme or intervention achieves the intended goals, objectives and targets or a beneficial result.
Efficiency	The relation between the outputs and the inputs used.
Enforcement	Actions that are 'taken at the individual organizational level to change their performance to comply with the legal requirements, e.g. when the inspecting organization follows up to make sure that necessary changes are implemented when nonconformities are encountered during an inspection' (Hovlid et al., 2015, p. 2).
Governance	The process by which the members of a hospital board (or a similar governing body) establish policies and continuously monitor their implementation.
Health Board	An NHS organisation in Wales, also called Local Health Board, University Health Board or Teaching Health Board, that comprises functions of commissioning and providing healthcare to patients within certain geographical boundaries.
Healthcare Commission	A short name for the 'Commission for Healthcare Audit and Inspection'.
Healthcare managers	Employees with managerial responsibilities working within an NHS, independent and other non-NHS healthcare organisation. This includes nursing directors of a LHB or NHS trust, hospital managers and ward managers.
HIW reviewer	Any regular member of an HIW inspection team. This includes HIW review managers, peer reviewers and lay reviewers.

HIW manager	HIW employees with managerial responsibilities. This includes the senior management team and review managers.
Hospital	In this study, a synonym for ‘acute hospital’.
Impact	Relates to all consequences of an intervention, determined after a considerable period of time. Impact is the result of a complex set of conditions, some of which are external and not directly related to the intervention itself.
Independent hospital	An acute hospital that is not operated by the National Health Service, but by organisations that provide health services purchased by private individuals, health insurers and the NHS.
Independent hospital managers	Employees with managerial responsibilities, who work at independent sector hospitals. In this study also referred to as ‘independent managers’.
Indicator	A quantitative or qualitative variable used to describe, understand, compare, assess and evaluate or improve a system, process, project, organisation. Indicators typically relate to certain aspects of healthcare and management performance such as cost, quality and safety.
Input	Resources comprising personnel, materials, equipment, information and money, which are put in a process and which typically can be quantified.
Inspection	‘A mechanism of external oversight whereby experts make periodic visits to a regulated organisation in order to assess its performance’ (Sutherland & Leatherman, 2006, p. 46).
Inspector	Any regular member of an HIW inspection team. This includes inspection managers, peer reviewers and lay reviewers. A synonym is reviewer.
Leadership	The ability to direct a group of people or an organisation.
Lay reviewers	Members of an inspection team who are selected as representatives of the public. They are not permanently employed by the inspectorate and usually do not have a clinical/professional background in healthcare. They may have personal experience as healthcare users in a particular area, i.e. experts by experience.
Local Health Board	An NHS organisation in Wales that comprises functions of commissioning and providing healthcare to patients within certain geographical boundaries.
LHB managers	Employees with managerial responsibilities who work at any level within a local health board. This includes LHB nursing directors, hospital managers and ward managers.

NHS body	An NHS trust or Local health board.
NHS managers	Employees with managerial responsibilities within a local health board or NHS trust.
NHS organisations	NHS trusts and local health boards.
Nosocomial Infection	An infection acquired during hospitalisation. Primary examples of bacteria which can cause nosocomial infections are Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) and <i>Clostridium difficile</i> .
Organisational culture	The expectations, experiences, philosophy and values which prevail in an organisation and guide the behaviour of individual employees. This applies particularly to patient-centred care and service-oriented behaviour, concern for quality and safety as well as attendance and punctuality.
Outcomes	Results of operations, processes or systems, typically related to outputs. An outcome might not always be intended.
Output	A product or service generated as a direct result of an organisational process. Outputs are quantifiable and can be used as performance indicators.
Peer reviewers	Members of an inspection team selected for their clinical/professional background in healthcare.
Performance	At an individual level, staff performance refers to the accomplishment of a given task or job measured against a set of defined criteria or standards. At the organisational level, performance refers to the extent to which the intended outputs, goals or objectives have been achieved.
Program(me)	'A structured intervention to improve the well-being of people, groups, organizations, or communities. Programs vary in size, duration, and clarity and specificity of goals' (Weiss, 1998, p. 335).
Program(me) theories	<p>'The underlying rationales for regulatory policies and strategies and the design of regulatory regimes' (Walshe & Boyd, 2007, p. 1).</p> <p>'The mechanisms that mediate between the delivery (and receipt) of the program and the emergence of the outcomes of interest.' (Weiss, 1998, p. 57).</p>
Regulation	'A sustained and focused control exercise by a public agency over activities that are valued by a community' (Selznick, 1985, p. 363).
Review body	Any organisations that audit, review or inspect healthcare organisations. Examples are HIW, Wales Audit Office and Community Health Council.

Review manager	Typically, an HIW employee who leads an inspection team, which may include peer reviewers and lay reviewers. A synonym is inspection manager.
Reviewer	Any regular member of an HIW inspection team. This includes review managers, peer reviewers and lay reviewers. A synonym is inspector.
Risk	The likelihood that damage, injury or any other adverse deviation from a desired outcome occurs. This includes uncertain events or factors that - if occurring - are likely to undermine the hospital's outcomes in general or the health and safety of patients and staff in particular.
Stakeholders	Individuals or groups of people with a direct or indirect interest, who are affected by or involved in the decisions of an organisation, programme or intervention.
Standard	The level of quality against which the performance of the healthcare providers is measured. National standards in healthcare set the mandatory minimum level of clinical practice, inputs, outputs or outcomes. Developmental standards, in contrast, define a higher level of quality or performance and aim to promote change and quality improvement.
System	A set of processes in the organisation that are aligned to generate a particular set of outputs and outcomes according to a specific purpose. Typically, a system contains a structure with interrelated and interdependent elements, uses inputs or resources and operates according to methods, procedures or routines.
Theory-driven evaluation	'Any evaluation strategy or approach that explicitly integrates and uses stakeholder, social science, some combination of, or other types of theories in conceptualizing, designing, conducting, interpreting, and applying an evaluation' (Coryn, Noakes, Westine, & Schroeter, 2010, p. 201)
University Health Board	An NHS organisation in Wales, also called Health Board or Local Health Board, that comprises functions of commissioning and providing healthcare to patients within certain geographical boundaries.

1 Introduction

'If regulation was going to improve care, it would have done it by now. So it's time to improve regulation.' (Professional Standards Authority, 2015a, p. 11)

Regulation and inspection have a long history in the United Kingdom (UK), particularly in education and social care (Johns & Lock 2008; Martin 2008). Prompted by serious shortcomings in the NHS in the 1990s (Smith 1998; Beaussier et al. 2016), mandatory inspections were introduced to ensure a minimum level of quality and improve healthcare in the UK. This thesis explores how inspections work in practice, focusing on hospital care in Wales.

This chapter introduces the reader to the research idea and the key terms employed in the thesis. The overview at the end presents the structure and summaries of the thesis chapters.

The alleged conflict between the two objectives of regulation, quality assurance and quality improvement (viz. Shaw & Kalo 2002), prompted the author to review the existing evidence and conduct this research. The research idea further developed when the author recognised the inconsistencies and frequent changes of regulatory approaches in the UK (Ham, 2014). In many cases, the scientific evidence for reforms or redesigns of inspection regimes remains unclear. A better understanding of how regulatory inspections influence healthcare seems essential for designing and implementing more effective regulation.

The focus on hospitals in this research stemmed from the researcher's professional background and the priority that regulatory bodies typically attribute to hospitals as resources-intensive, high-risk settings. The Healthcare Inspectorate Wales (HIW) seems an appropriate choice, as HIW's inspection regimes have not been the subject of previous research. The thesis follows a qualitative approach and explores the nature of the inspections from the two main perspectives: the inspectorate and the inspected healthcare organisations. The realist theory-driven evaluation employed by the study is instrumental in analysing the specific components, mechanisms and settings, in which hospital inspections take place.

The research sets out to answer the following question:

What are the strengths and weaknesses of the inspection regimes that HIW has implemented in acute care hospitals in Wales?

The specific research questions are:

- I. How far have the inspection regimes been implemented and what specific problems have been encountered during implementation?
- II. Which elements and mechanisms have shown to be effective in which specific setting?
- III. What modifications to the regimes are likely to improve their effectiveness in a particular setting?

1.1 The inspection regime

HIW (2015a) describes itself as 'independent inspectorate and regulator of all health care in Wales'. The concepts of regulation and inspection are central to this research. Numerous definitions of regulation can be found in academic literature. Amongst the most cited definitions are the following: according to Selznick (1985, p. 363) regulation is 'a sustained and focused control exercise by a public agency over activities that are valued by a community'. Contrastingly, James (2000, p. 327) defines regulation as 'achieving public goals using rules or standards of behaviour backed up by sanctions or rewards of the state'. Black (2002, p. 20) more comprehensively perceives regulation as an 'attempt to alter the behaviour of others with the intention of producing a broadly identified outcome or outcomes'.

From the various definitions and interpretations, the following features of regulation have been extracted and employed in this thesis:

1. Formal remit, which entails a range of sanction and reward mechanisms to influence behaviour,
2. Central oversight,
3. Monitoring performance according to rules or standards,
4. Third-party accountability, separation between regulating and regulated organisations,
5. Orientation to explicit public goals and/or an implicit public interest.

These are put into practice through the inspection regime. Inspection refers to a method or process typically employed in regulation. The thesis uses the terms inspection regime and regulatory regime, which Walshe and Boyd (2007, p. 22) define as a 'set of processes or interventions which the regulator puts in place in order to regulate.' Walshe (2003, p.33) identifies three functions:

'Direction	The methods used to communicate regulatory requirements or directions to regulated organisations
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Detection	The methods used to measure and monitor the performance of regulated organisations to determine whether they comply with regulatory requirements or direction
Enforcement	The methods used to persuade, influence or force regulated organisations to make changes to comply with regulatory requirements or directions’.

The regulatory regime is typically presented as a set of three functions. At the same time, the inspection regime can be perceived as a process or set of interconnected processes. This thesis distinguishes three major stages of the entire inspection regime: the pre-inspection, the on-site inspection and the post-inspection processes. The thematic framework employed by this thesis reflects this process approach and guides the structure of the thesis.

1.2 The structure of the thesis

The thesis has been divided into three main parts:

Part I. Research context

The first part describes the context in which this evaluation is embedded.

Chapter 2 Hospital inspections

The literature review discusses the results of previous hospital evaluation studies and the methodological difficulties in evaluating organisational performance and hospital inspection regimes. Moreover, the researcher examines existing programme theories and theoretical frameworks regarding their potential to inform and support this evaluation research.

Chapter 3 Methodology

This chapter outlines the evaluation approach, strategy and methods chosen to answer the research questions. The chapter outlines the activities undertaken to ensure a thorough and systematic research process. The chapter also presents the theoretical framework used in the data analysis.

Part II. Hospital inspections – HIW's perspective and the hospital managers' views

The chapters in Part II present the main findings, structured according to the aforementioned theoretical framework.

Chapter 4 Inspecting

Here the researcher presents the findings from the document review and the interviews with HIW managers and reviewers. This encompasses HIW's views on how its inspections are supposed to be conducted and become effective.

Chapter 5 Being inspected

This chapter contains the main findings from the interviews with NHS and independent healthcare managers from Wales, who describe how inspections were conducted at their hospitals. This includes difficulties and impacts that managers encountered.

Part III. Reflection

Part III critically reviews the findings from the interviews and document reviews that are presented in Part II.

Chapter 6 Effective elements and mechanisms of HIW's inspection regimes

Chapter Six discusses the findings of this thesis. Particularly, it reviews the mechanisms of how the various elements of HIW's inspection regimes become effective and compares the findings with other studies.

Chapter 7 Conclusions

The final chapter contains the main conclusions and recommendations as well as implications for future research.

Part I. Research context

The first part of the thesis contains two chapters, which describe the context in which this research is embedded. Chapter Two contains the literature review, which summarises the results and the methodological difficulties of evaluation studies in the healthcare sector. The methodology chapter presents the approach, strategy and methods which were employed in this evaluation study.

2 Hospital inspections

This chapter summarises the theoretical and empirical literature which informed this study. It includes an overview of key concepts, published findings on regulatory effectiveness and the difficulties in evaluating hospital performance and inspection regimes. Moreover, the literature review examines theoretical frameworks and assumptions of how inspection regimes work.

2.1 Searching for literature

A staged process was employed in the literature search and review comprising the following steps:

1. Familiarising with the major theories
2. Structuring the overview in a draft literature review
3. Regular updating and refinement
4. Finalising the literature review with regard to the research findings

The first literature searches, conducted between October 2011 and May 2012 in the Web of Knowledge and Pubmed/Medline, employed the following search terms:

- Inspectorate OR commission OR HIW OR CQC OR CHAI OR NHS OR regulator*
- Perform* OR compliance OR deterren* OR effectiveness OR quality OR accountab* OR achievement OR cleanliness
- Inspect* OR assess* OR scrutin* OR examin* OR stud* OR review OR visit OR evaluat* OR regulation OR audit
- Standard* OR indicator* OR target* OR objective*
- Hospital*
- United Kingdom OR Wales OR England OR Great Britain,

Only 30 scientific articles of some relevance were detected. After the first strategy, which exclusively relied on publications in peer-reviewed journals, had yielded limited results, the researcher employed a wider search strategy using various tactics to identify relevant literature. This included

- Searching the reference lists and citations of publications
- Searching and identifying relevant articles and authors in journals and anthologies
- Approaching experts, practice-based supervisors and peers for relevant literature and authors
- Searching for previous or later work of authors, whose articles were identified through the initial search, citation and reference lists and other ways. This

included looking at university websites for particular authors (e.g. Kieran Walshe, John Braithwaite).

- Using regular publication alerts such as JAMA, BMJ and Researchgate – to identify new articles about healthcare regulation, inspection and quality
- Searching and accessing relevant literature via the catalogues of Frankfurt and Bath university libraries, the browsers of Google, Google scholar and Google books, BMJ, ResearchGate, Endnote and Mendeley
- Visiting potentially relevant websites such as Cochrane library, Kings Fund, Health Foundation, HIW, CQC, Monitor, EPSO and Welsh government.

This wider search for literature yielded many relevant documents, including grey literature such as evaluation reports. It appeared that some of the most relevant studies (Day & Klein, 2004; Sutherland & Leatherman, 2006; Walshe, Addicott, Boyd, Robertson, & Ross, 2014) were not published as peer-reviewed journal articles. The search for literature and updating continued throughout the study.

Initially, the literature search had focused on healthcare inspections. In the course of the reading, the researcher widened her perspective and her search towards the themes of regulation, regulatory theories, performance and effectiveness, healthcare quality, public service and reforms in UK. This helped to gain a broader understanding of the researched area and the context in which inspections take place.

In preparation of the research protocol, the researcher then explored the literature on suitable research and evaluation methods. This included textbooks and articles about the case study method, evaluation methods, programme theory and reports of applied evaluation. Reviewing the literature informed the choice of realist evaluation as evaluation method.

At a later stage, the focus shifted to particular change models and mechanisms. The specific literature searches aimed to inform the reconstruction of the change mechanisms related to particular inspection elements such as healthcare standards, registration, self-assessment, peer-review, feedback, reporting, action plan and follow-up. The mechanisms, elements and their synonyms were used as search terms. For example, search terms related to action plans included: action plan, improvement plan, corrective action, implementation, improvement.

The literature review, data extraction and synthesis proceeded in an iterative manner. This included making notes and highlighting essential information in the original text and extracting data and tables, citing relevant phrases, critically reviewing and summarising thoughts and information in separate word documents. The notes and summaries were instrumental in the preparation of specific paragraphs and draft literature chapters. Initial literature review chapters covered in large parts theories of regulation and the political

context of regulation and devolution in UK. The draft versions were modified and shortened several times, before the final literature review appeared in the current shape.

The following review comprises the essence of the studied literature and how it informed the content and design of this study. The literature is reviewed in four main sections. The first sets the scene with a general overview of the regulation literature. The second summarises the specific literature on healthcare regulation, which explores regulatory effectiveness and the difficulties in measuring effectiveness. The third examines theoretical frameworks for the evaluation of regulatory regimes in order to develop a framework for this research. The fourth seeks to identify the change mechanisms in the process of inspection.

2.2 Regulation theories

This section sets the scene with a general overview of the regulation literature and describes the shift from descriptive to prescriptive theories.

The boom in regulation, which various authors describe as ‘golden age of regulation’ (Walshe, 2003, p. xi), ‘audit explosion’ (Power, 1994) and ‘inspection explosion’ (Martin, 2010, p. 18), has been accompanied by a growing body of theoretical literature. Many regulation theories are descriptive, i.e. portraying the development and rationales of regulation. This includes:

- Public interest theory, which regards regulation as a means to achieve desired results in the public interest, where the market otherwise would fail. The approach postulates ‘dispassionate expertise’ of the regulator and ‘objective standards’ (Baldwin, Cave, & Lodge, 2012, p. 41).
- Interest groups theories which argue that regulation is driven by particularistic concerns.
- Institutionalism, which deals with questions of the institutional design and relations, such as the principal-agent-theory.

The latter two are predominantly concerned with examining dysfunctions and unintended consequences of regulation (Stigler 1971; Berry 1982; James 2000; Walshe 2003; Downe & Martin 2007; Baldwin et al. 2012a), such as:

1. Ineffectiveness due to regulatory ‘capture’
2. High cost, which decreases efficiency in the industry
3. Goal displacement and proliferation: regulation creates more regulation which is in the regulator’s self-interest
4. Ossification: compliance with predefined standards hinders innovation and improvement

5. Stabilisation of monopolistic or oligopolistic structures by limiting market access for potential producers or service providers
6. Unaccountability: the regulator lacks accountability/legitimacy
7. Juridification: involvement of lawyers and appeals to courts.

Due to a shift in paradigms, described as 'Zeitgeist has changed' (Walshe, 2011, p. 516), regulation has become commonly accepted as 'necessary for the functioning of a market economy and public services' (Baldwin et al., 2012, p. 9). In consequence, the focus moved towards prescriptive theories. As Table 1 shows, normative regulatory theories initially focused on either compliance or deterrence approaches.

TABLE 1 THE DETERRENCE – COMPLIANCE CONTINUUM

Deterrence		Compliance
Detection, apprehension and punishment for breaching rules	General strategy	Bargaining, conciliation and negotiation to attain results, prevent or repair harm
Legalistic, accusatory style; Poor and antagonistic	Style and relationship	Informal, conciliatory style; Friendly and cooperative
'Amoral calculators' dominated by their self-interest, need to be watched carefully	Image of regulated organisations	'Good-hearted compliers', sharing the regulator's objectives, worthy of trust and support
'Policeman': applying formal standards, inspections, penalties	Regulators' role	'Politician' or 'consultant': persuading, advising, educating
Large number of organisations -> distance	Prevalence in sectors with	Small number of organisations -> building long term relationships
Speedy change; more effective with small & medium size organisations	Advantage	Securing cooperation and support, more sustainable, long-term commitment to improvement, less costly
Costly; may provoke a 'culture of regulatory resistance'	Disadvantage	Some organisations may circumvent & not comply; the lack of severe consequence, undermines the morale of other organisations and disadvantages consumers

Source: Adapted from Kagan & Scholz 1984; Braithwaite et al. 1987; Black 2001; Walshe 2003; Gunningham 2015

This dichotomy, which can be perceived as a two ends of a continuum of regulatory behaviour (Braithwaite et al., 1987; Walshe, 2003), has been succeeded by 'better regulation initiatives' (Baldwin et al. 2012a, p.9), labelled as

- 'responsive' (Braithwaite, 2011),
- 'smart' (Gunningham, Grabovsky, & Sinclair, 1998),
- 'right-touch' (Professional Standards Authority, 2015b),

- 'risk based' (Beaussier et al. 2016),
- 'proportionate' (Prosser, 2010) or
- 'hybrid' (Mcdermott, Hamel, Steel, Flood, & Mkee, 2015).

Better regulation refers to different prescriptive approaches that aim to design regulatory systems which (i) more effectively achieve the intended objectives in the public interest and (ii) prevent regulatory failure. Prescriptive regulation theories are of practical importance in that they may support the legislators/regulators in their efforts to design new or reform existing regulatory systems.

2.3 Healthcare regulation

This section summarises the specific healthcare regulation literature, the (re)search for regulatory effectiveness and why effectiveness is so difficult to assess in healthcare.

With the pursuit of more effective regulation, publications increasingly differentiate amongst different industries and regulatory goals. Unlike many other sectors, where regulators pursue economic, market-regulating objectives, the nature and rationale of most regulation in healthcare is predominantly social (Walshe, 2003). Walshe (2003) and Sutherland and Leatherman (2006, p. 7) list three main objectives for healthcare regulation:

1. Improvement, i.e. better performance and quality of care for patients through changes in practice
2. Assurance that minimally acceptable standards of quality, safety and effectiveness are achieved
3. Accountability for performance and financial resources, 'empowering patients, users and the public in their interaction with healthcare organisations and professionals' (Walshe, 2003, p. 170).

Further objectives may include: (i) patient safety (Healy, 2016) and (ii) informing government policies and decisions (Day & Klein, 2004; Welsh Assembly Government, 2009).

Compared to clinical research, studies on regulatory interventions form a relatively small body of research literature (Bardsley, 2016; Healy, 2016). The two meta-analyses on regulatory interventions and/or inspections in healthcare, which the literature review identified, searched for evidence of regulatory effectiveness (Flodgren, Pomey, Taber, & Eccles, 2011; Sutherland & Leatherman, 2006).

In a systematic review, Flodgren and colleagues (2011) sought evidence of improvements in organisational and professional behaviour as well as patient outcomes resulting from external compliance inspections. The assumption was that mandatory

inspections have a positive effect on hospital performance due to the deterrence of expected negative consequences of noncompliance. Amongst the 9901 titles retrieved in the initial stage, only two studies fulfilled the review criteria, one from South Africa, which showed some effectiveness, and one from the UK conducted by the Office for Public Management (OPM)¹. The latter, an interrupted time-series study, did not show a significant difference between the number of hospital-acquired MRSA² cases before and after the inspection programme started. Conversely, recent field studies in UK hospitals showed that self-reported infection rates cannot be regarded as entirely objective measures of incidence (Dixon-Woods, Myles, Bion, & Tarrant, 2012; Limb, 2012).

In their review of 'regulation and quality improvement', Sutherland and Leatherman (2006) identified three studies on the effectiveness of inspections: one about US hospital inspections (Gibbs Brown, 1999), two concerning the former Commission for Health Improvement (CHI) in UK (Benson, Boyd, & Walshe, 2004; Day & Klein, 2004). Both evaluation studies, which employed, however to varying extents, interviews, surveys and document analysis, provide a comprehensive view on CHI inspection activities and their impact.

In a three-year study, Day and Klein (2004, p. 10) highlight the challenges and dilemmas of CHI's inspection regime, which they portray as a 'process of experiment, adjustment and change'. While the authors acknowledge CHI's productivity, they raise concerns about the appropriateness of the clinical governance framework for the ratings, the variability in data analysis, reporting as well as the composition and expertise of inspection teams. In the absence of formal enforcement powers, CHI's role was judged as more 'diagnostic' and 'catalytic', rather than 'therapeutic'. The issues which CHI inspections detected were often known to the healthcare managers. The prospect of poor rating and reporting urged the inspected organisation to tackle those issues more rapidly. Overall, Day and Klein (2004, p.35) evaluated CHI's impact as 'diffuse and indirect'.

Benson and colleagues' (2004) findings widely concur with the above study: inconsistencies in CHI reports, review methods and review teams. While the authors found evidence of positive impact from CHI inspections, they saw room for improvement in various areas. This included more explicit standards; training and selection of review teams; clear, specific and reasoned recommendations; thorough follow-up and frequent feedback on performance. In their literature review, the authors – compare Walshe

¹ The OPM study remained inaccessible and could therefore not been included in the current literature review.

² Methicillin-resistant *Staphylococcus aureus* (MRSA) is a bacterium, which can cause hospital-acquired infections.

(2003, p.163f.) and (2008, p. 81) - summarise reported positive effects of healthcare regulation on organisational performance:

- Improvements in patient care resulting from regulatory attention
- Organisational reflection sparked by comparison of performance
- Changes in organisational priorities
- Providing leverage for change to internal stakeholders
- Driving continuing improvement due to regularly updated standards.

The effects relate to changes made by the regulated organisation (i) in the knowledge of the existence of the regulator and regulatory instructions, (ii) in the expectation of an inspection, (iii) in direct connection with an inspection or other regulatory intervention or (iv) as an indirect consequence.

In an attempt to synthesise the findings, Sutherland and Leatherman list five factors, which they claim to be generally agreed as contributing to effectiveness. These overlap with some of the 'principles of inspection' developed by the Office of Public Services Reform (OPSR) (2003, p. 34), as Table 2 shows.

TABLE 2 SYNOPSIS: PRINCIPLES AND FACTORS OF EFFECTIVENESS

Factors contributing to effectiveness	Comparison	The 10 OPSR principles
Expertise of inspectors	Similar, but not identical	<ul style="list-style-type: none"> • Inspectors should continually learn from experience
Clear goals for inspection regime	Similar, but not identical	<ul style="list-style-type: none"> • The purpose of improvement
Balance local flexibility with national standards	No equivalent	
Clear goals for inspected organisations	No equivalent	
Proportionality in terms of costs and risks	Similar	<ul style="list-style-type: none"> • Proportionate to risk • Inspectors should have regard for value for money, their own included
	No equivalent	<ul style="list-style-type: none"> • A focus on outcomes • A user perspective • Inspectors should encourage rigorous self-assessment by managers • Inspectors should use impartial evidence • Inspectors should disclose the criteria they use to form judgments • Inspectors should be open about their processes, willing to take any complaints seriously, and able to demonstrate a robust quality assurance process

Source: Adapted from Sutherland and Leatherman 2006 and Office of Public Services Reform 2003

More evidence of regulatory effectiveness could have been expected with regard to the growing importance of healthcare regulation. Although Flodgren and colleagues do not exclude a publication bias, it seems reasonable to assume that the paucity of selected studies in their and Sutherland and Leatherman's review results from the rigid selection criteria and a positivist-reductionist stance.

Many authors have explicated the fundamental difficulties of evaluating quality improvement interventions (Øvretveit & Gustafson 2002; Grimshaw et al. 2003; Walshe 2003; Leatherman & Sutherland 2008; Flodgren et al. 2011; Braithwaite 2014). These mainly relate to the

- (i) Complexity of organisational effectiveness
- (ii) Difficulties of measurement
- (iii) Complexity of real-world interventions and
- (iv) Research designs.

(i) The complexity of organisational effectiveness

Organisational effectiveness and performance relate to complex concepts, which are objectively not definable and 'compounded by the lack of theoretical consensus' (Talbot, 2010, p. 148). This equally applies to healthcare quality, which embraces multiple perspectives, expectations and dimensions (Berwick, 2002; Cowing, Davino-Ramaya, Ramaya, & Szmerekovsky, 2009; B. C. James, 1989; Øvretveit, 1997).

This ambiguity poses the central question: what to assess the regulator against? Although 'it might be very proper to judge regulators according to their success in fulfilling their mandates' as Baldwin and colleagues (2012, p. 27) explain, they admit that: 'Most regulators statutes give regulators broad discretions'. Moreover, enforcement functions are often distributed amongst different regulating bodies (Baldwin & Black, 2008), as in the case of HIW. Healthcare regulation goals are unstable, difficult to define and often competing (Beaussier, Demeritt, Griffiths, & Rothstein, 2015), such as accountability versus organisational learning and improvement (Dodds & Kodate, 2011). Furthermore, regulatory effectiveness needs to consider the resources spent, i.e. regulatory efficiency.

(ii) The difficulties of measurement

For the purpose of evaluation, objectives, targets or service standards need to be specified in measurable terms, though not all aspects are 'readily quantifiable' (Raleigh & Foot, 2010, p. 4). As the selection of indicators is 'politically contentious' (Beaussier et al., 2016, p. 4), ideally, they should reflect the values of the key stakeholders (Shaw, 2003a). Results may vary across the sometimes-conflicting performance dimensions.

Aggregated performance data at hospital or NHS trust level are likely to mask variation in healthcare quality across different departments and units (Nuffield Trust, 2013).

A disputed question in performance assessment is the choice between input/structure, process, output and outcome indicators. Their usefulness depends on the particular measurement aim and purpose (Baldwin & Black, 2008). Although Donabedian (2005, p. 694) described outcomes as 'the ultimate validators of the effectiveness and quality of medical care', their predominant use in evaluation is problematic from a hospital's viewpoint due to confounding effects of time-lags and co-morbidities (Raleigh & Foot, 2010). Comparison and generalisation are impaired by differences and variability in data sets, which evaluators use to measure inputs, process and outcomes, and data collection methods. Thus it becomes a matter for speculation 'whether the observed changes result from real change in performance or changes in data collection' (Walshe, 2003, p. 160).

Bevan and Cornwell (2006, p. 365) comment on the 'formidable difficulties' of relying exclusively on statistical data that are 'routinely available'. Several authors (Clarke & Dawson, 1999; Walshe & Phipps, 2013) point at the potential for inspection to generate data that can be used to serve the purposes of evaluation. In this respect, published inspection reports represent a potential opportunity for secondary data analysis. However, the changes in HIW's inspection regimes, reporting and staff impede the comparison. Moreover, inspections of one hospital ward over one or two days do not necessarily represent the performance of all wards at all times.

(iii) The complexity of real-world interventions

Regulatory interventions take place in natural settings (Pawson, Greenhalgh, Harvey, & Walshe, 2005; Walshe, 2007), typically concurrent with other, interrelated interventions (Ham, 2014; Øvretveit & Gustafson, 2002). The context, content and variables in implementation make it extremely difficult, if not impossible, to objectively relate changes in healthcare outcomes or other effects to one single intervention (Bate, Robert, Fulop, Øvretveit, & Dixon-Woods, 2014; Ham, 2014). Variables in real-world settings, unlike in laboratory experiments, are not under full control. This particularly relates to the inspections themselves, which entail many, interrelated processes, actors and elements. Benson and colleagues (2004) refer to methodological difficulties caused by the changes in CHI's review process and reporting structure as well as to the changes in staff responsibilities at the hospitals.

Last but not least, the evaluation may fail to realise that an intervention was not implemented as planned or documented (Øvretveit & Gustafson, 2002).

(iv) Research designs

Various authors have commented on the suitability of certain research designs (Boaden, 2011; Øvretveit & Gustafson, 2002). The fact that all healthcare organisations in the UK are subjected to regulation excludes an experimental design comparing regulated and unregulated hospitals. Walshe (2003) suggests instead examining the changes in performance of regulated organisations over time, if possible before and after the regulatory intervention. Observational studies are according to Sutherland and Leatherman (2006) the preferred methodology to identify research evidence about regulatory impact. Boaden (2011, p. 503), referring to the potential sources of bias and confounding, notes that most research papers on quality improvement are 'descriptive studies rather based on a single site than analytic reviews'. Some evaluation studies attempt to mitigate the inherent difficulties by employing mixed methods (Benson et al., 2004; Day & Klein, 2004).

Not surprisingly, regulators' own reports are very likely to state a positive impact of regulation and inspection (J. Dixon, 2011). Some scholars therefore argue for independent evaluations and distance (Walshe, 2003). This thesis with the researcher not being employed, commissioned or funded by any regulatory body fulfils the criterion of 'distance'. The downside of this distance is, however, the lack of inside knowledge and experience. A practical solution to combine distance and regulatory expertise could be external evaluations conducted by peer evaluators from similar inspection bodies. The example of the peer evaluation of the Norwegian Board of Healthcare Supervision conducted by the European Partnership of Supervisory Organisations in Health Services and Social Care (2012) indicates, however, two potential weaknesses. Firstly, the funding of the study by the evaluated body may compromise the independence of the evaluators. Secondly, the absence of a researcher and lacking information about evaluation methods and tools raise concerns about methodological rigor.

2.4 Theoretical frameworks

This section examines the more theoretical literature in order to help develop the framework for this thesis. Several frameworks, which were identified as potential tools and structural guidance, are presented below.

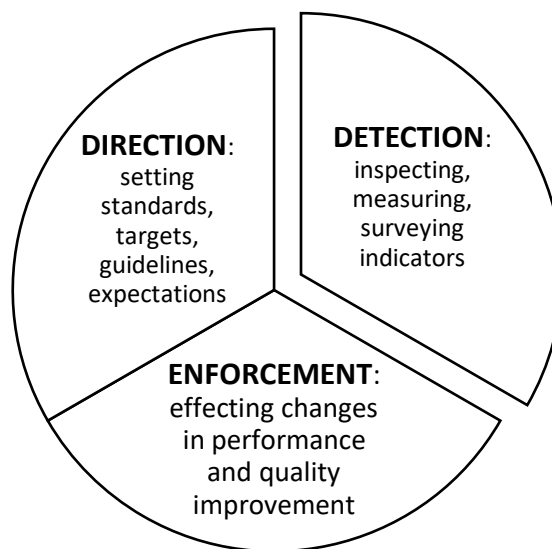
In their study on external reviews of healthcare organisations, Walshe and colleagues (2001) examine five aspects: the purpose, organisation, overall approach, methods and results. Walshe (2003) further elaborated this framework:

1. Regulatory organisation
2. Regulatory goals/objectives
3. Scope of regulation

4. Regulatory model
5. Direction
6. Detection
7. Enforcement.

In a later publication, Walshe and Boyd (2007) suggest a similar framework. The core of this framework, the three elements of the regulatory regime, resemble Shaw's (2003b) 'Cycle of quality improvement', which is depicted in Figure 1.

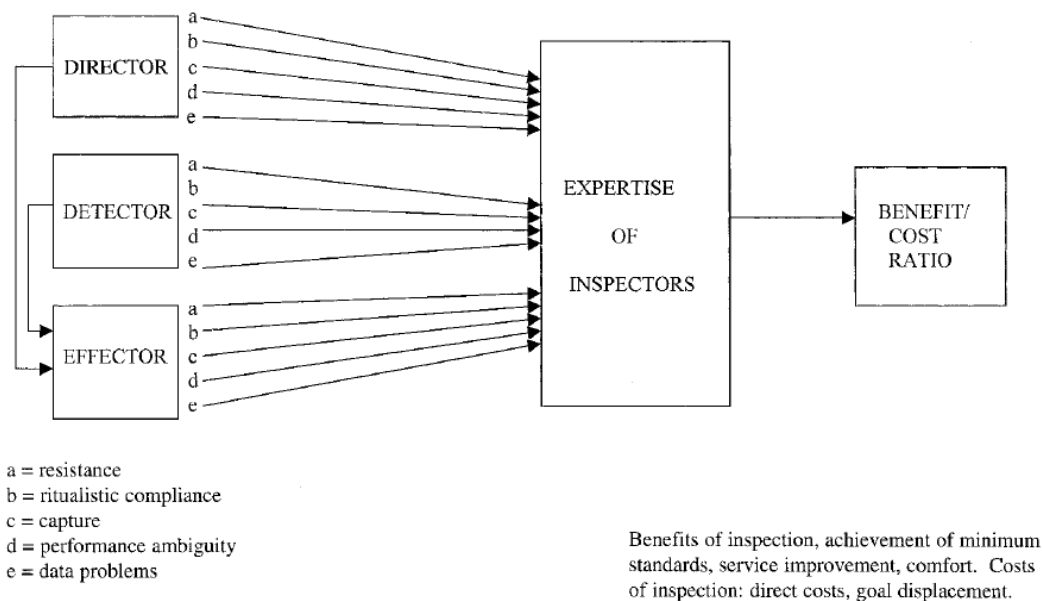
FIGURE 1 THE CYCLE OF QUALITY IMPROVEMENT APPLIED TO REGULATORY INSPECTIONS



Source: Shaw 2003b

In their theoretical framework, see Figure 2, Boyne and colleagues (2002) relate the elements of the regulatory regime with 'five potential problems'. According to this framework, the expertise of inspectors as a mediating variable is central for regulatory effectiveness. While inspectors are undoubtedly crucial, the framework seems to disregard other relevant factors. Boyne and colleagues' framework transcends the role of pure structural guidance and reduces complexity far less than other frameworks.

FIGURE 2 RELATIONSHIPS BETWEEN THE VARIABLES IN THE THEORETICAL FRAMEWORK



Source: Boyne and colleagues 2002

Conversely, Walshe's (2007) proposed framework for a theory-driven evaluation of quality improvement interventions considers the context, content, application and outcomes. In the publication 'Developing a strategic framework to guide the Care Quality Commission's (CQC) programme of evaluation', Walshe and Phipps (2013) reconstruct CQC's regulatory model and the underlying assumptions which shaped the regulatory design. More specifically, they examine the components of standard setting, risk-based regulation and the regulatory workforce. The report on the evaluated inspections in 2014 (Walshe et al., 2014), however, employs a slightly different structure:

- The logic of the model
- Preparation for inspection
- Inspection teams and how they work
- The process of inspection
- Ratings and reports
- After inspections: actions and impacts.

The structure predominantly follows a sequential order: (i) the activities before the actual inspection, (ii) the on-site visit and (iii) the activities, outputs and outcomes after the inspection. Due to their important role throughout the process, inspection teams are analysed separately. A similar process-oriented framework was developed for this thesis (viz. 3.3 Analysis).

2.5 Change mechanisms

This section seeks to identify possible change mechanisms in the process of inspection. Knowledge of these mechanisms helps to evaluate HIW's inspection regime (viz. methodology chapter). In the absence of explicit programme theories, the researcher made initial assumptions by reviewing relevant publications and interviewing stakeholders (Posavac, 2010). She reviewed several papers which develop and test theories of how the regulatory regime and its components work.

Basically, healthcare regulators aim to influence the behaviour of the regulated organisations (Walshe, 2003). If the underlying assumptions hold true, inspection regimes are expected to influence changes in behaviour at individual, group and organisational level and thus improve organisational performance and healthcare quality (Walshe & Boyd, 2007).

Regulation relies on various mechanisms which, in combination with specific contextual factors, produce desired outputs and outcomes (Pawson & Tilley, 1997). Since not all circumstances generate these effects (Grol & Wensing, 2004), it is important to analyse in more detail the content, mechanisms and contextual factors. These aspects are often neglected in study reports (Kringos et al., 2015) and are insufficiently understood (Bate et al., 2014; Kaplan, Provost, Froehle, & Margolis, 2012). Empirical research, such as this thesis, may serve the practical purpose of investigating these aspects in order to 'establish when, how and why an intervention works' (Walshe, 2007, p. 58), the evidence of which can then be used to improve the system.

The following elements and presumed working mechanisms have been extracted from the reviewed literature and grouped according to their prevalence in the regulatory process. It needs to be noted that the multiple functions of certain components such as inspection teams complicate an unambiguous attribution to particular parts of the inspection regime or process.

2.5.1 Pre-inspection

Components which may influence the behaviour of the regulated organisations prior to the actual on-site inspection are the (i) standards and rules, which regulated organisations are supposed to comply with, (ii) registration of healthcare organisations through the regulator, (iii) self-assessments, which the regulated organisation conducts and shares with the regulator as well as (iv) selection of inspection sites and pre-inspection information, which may influence the location, time, frequency and focus of inspections.

(i) Standards

To assess the organisations against, healthcare regulators use rules, standards and criteria. According to Walshe and Phipps (2013) standards in regulation (i) determine stakeholders' values and performance expectations, (ii) promote self-enforced compliance which leads to improvement, (iii) are instrumental in measuring and enforcing compliance and (iv) help to compare performance and differentiate between providers.

The literature distinguishes between minimal, average and ideal (i.e. maximal or optimal) standards (Shaw & Kalo, 2002) as well as generic and specific standards (Walshe, 2003). Minimal standards intend to ensure a defined minimum of quality by sifting out the 'bad apples' (Shaw, 2003b, p. 116). However, they fail to drive innovation and further improvement amongst organisations that meet the minimum requirements (Walshe 2003; Shaw 2003a). The ambiguity of generic statements leaves room for interpretation and, potentially, disagreement. Counterintuitively, previous research found fewer, broadly formulated standards to be preferable for inter-reviewer reliability than a larger number of very specific standards (Braithwaite & Braithwaite, 1995). Guiding literature stresses the importance of evidence-based standards and criteria for effective improvement of healthcare and acceptability amongst the (clinical) stakeholders (Gray, 2001; McGlynn, 2003; Veillard, Guisset, & Garcia-Barbero, 2004). Regulated organisations presumably find it easier to comply with standards that they consider appropriate or reasonable (Kagan & Scholz, 1984). It is therefore advisable to design a regular, fair and transparent standard setting process, which involves the stakeholders (Walshe 2003; Hilarion et al. 2009). Similarly, Berwick and colleagues (2013, p. 30) plead for the involvement of patients, carers and the public in the development of what they called 'principle-based standards'. Conversely, hospitals with insufficient capabilities may require additional resources and support to adhere to standards.

The difficulties of defining standards as quality measures have been highlighted above (viz. 2.3 Healthcare regulation).

(ii) Registration

Registration potentially contributes to regulatory effectiveness through various mechanisms:

- Firstly, registration requirements can act as a threshold for new providers by deterring inept providers or denying them access to the market. Other applicants will increase their efforts to meet the requirements (Walshe & Phipps, 2013).

- Secondly, by building trust or 'low distrust' (Rousseau et al., 1998, cited by Six 2013, p.166) and common understanding of performance requirements the registration process can initiate a constructive regulatory relationship, which will promote current and future compliance (Walshe & Phipps, 2013).
- Thirdly, the data provided by the registering organisation can serve as baseline for future inspections, help to assess risk levels and thus inform future interventions (Commission for Healthcare Audit and Inspection, 2009).
- Fourthly, the threat of a potential deregistration is a powerful enforcement tool (Commission for Healthcare Audit and Inspection, 2009).

(iii) Self-assessments

Self-assessment constitutes a modern technique (Office of Public Services Reform, 2003) or, as Jewell & Wilkinson (2008) enthusiastically declared, a 'radical new approach' in regulatory regimes. Supposedly, self-regulation reduces the need for and frequency of (costly) external inspections and makes regulation more effective through the following mechanisms:

Shifting the primary responsibility for quality assurance to the regulated organisation allegedly increases ownership (Thomas 2013) and reflexivity (Hood, James, & Scott, 2000). The regulated organisation identifies the relevant gaps, takes corrective action and thus improves compliance/performance (International Finance Corporation, 2010). Self-assessment, which actively involves the entire workforce, has the potential to enhance internal communication and common understanding about performance issues and improvement techniques (Carnino, 2000).

Moreover, self-assessments and self-reported data inform regulatory decisions and targeted inspections (Jewell & Wilkinson, 2008; Walshe & Phipps, 2013). While self-assessments may reduce the burden of external inspections, they create an additional organisational burden within the regulated organisation (Scrivens, 2007). The regulated organisation needs to have the capacity and resources to install systems to control and improve performance. Supposedly, regulatory site-visits can serve as a 'reality check' of how such internal systems work in practice (Day & Klein, 2004, p. 10). Implementation deficiencies became, however, apparent at Mid Staffordshire, when inaccurate self-assessments were relied upon and not thoroughly tested (Francis, 2013). With regard to similar failings of CHI concerning Maidstone and Tunbridge Wells trust, Bevan (2008, p. 97) rated self-assessment as an 'inadequate tool for regulation'.

(iv) Selection of inspection sites and pre-inspection information

In theory, regulators may choose to inspect a particular organisation either (i) regularly, as part of an all-inclusive inspection cycle, (ii) randomly, (iii) purposefully, by targeting high-risk services and poor performers or (vi) representatively, selecting a broad spectrum of presumably strong, medium and poor performers.

In the past, regulators such as CHI used to inspect all NHS trusts during one inspection cycle. Increasingly, targeted, risk-based inspection approaches have become very popular, aiming to concentrate the limited resources on detecting poor performers (Adil, 2008; Black & Baldwin, 2012; Hampton, 2005; Tombs & Whyte, 2013). Regulatory regimes, which purposefully target poorly-performing organisations, intend to incentivise good performers by reducing the regulatory burden and, by making the regulated organisations aware of the selection principles, stimulate quality improvement (Walshe & Phipps, 2013). The difficulty, however, lies in the mechanisms and data to identify poor performing hospitals *ante inspectionem* (Bardsley, 2016; Beaussier et al., 2016; Griffiths, Beaussier, Demeritt, & Rothstein, 2016). Moreover, the prospect of preferential treatment may tempt providers to embellish or manipulate self-assessed/reported data (Shaw, 2003a).

2.5.2 On-site visit

The literature describes several mechanisms on how regulatory visits can drive change and improvement.

Improvement prior to announced or anticipated inspection: As explained above, the prospect of an inspection and the fear of exposure can impel healthcare managers to examine and resolve compliance/performance issues (Day & Klein, 2004; Walshe & Phipps, 2013). This is the case for announced inspections, which leave ample opportunity for preparation, and those that follow a routine schedule (Walshe & Boyd, 2007). The impression of an imminent visit can also be created through intensive media reporting.

Improvement through diagnosis, dialogue and enforcement: inspections are the only option for the regulator to check how far the healthcare organisation conforms with standards and best practice. On-site visits constitute the core element of the regulatory regime with regard to the diagnosis of compliance/performance and the dialogue with healthcare providers (Kilsdonk, Siesling, Otter, & van Harten, 2016). Though healthcare organisations can be expected to have more inside knowledge, they may lack the capacity or systems to analyse the voluminous data and take informed actions. The independent perspective and expertise of external reviewers can provide fresh ideas and valuable advice, equal to a 'free consultancy' (Walshe et al., 2014, p. 67). Detected noncompliance will be the subject of subsequent improvement / enforcement activities.

External lever for internal improvement: certain (internal) stakeholders may use (i) the inspections as the 'big bad wolf' (Walshe et al., 2001, p. 373) and (ii) inspection results as an extra lever to convince other (internal) stakeholders to accept organisational change (Day & Klein, 2004).

Regulators can use a variety of options to modify the characteristics and thus the effectiveness of on-site visits. This primarily concerns the inspection design or methodology and the composition of the inspection team.

Scope and themes: inspections can either look at a large range of healthcare aspects or focus on certain standards, complaints or themes. The latter often relates to high-risk areas and vulnerable patient contingents, such as elderly people (Healy, 2016). Moreover, the regulator decides whether to investigate clinical practice or governance systems or a combination of both (Day & Klein, 2004).

Frequency, timing, and duration: regulators determine how often, when and for how long they inspect an organisation. In theory, a high frequency (Ivers et al., 2012), irregular times, such as week-ends and nights (NHS Wales & Welsh Government, 2014a), and extensive site-visits (Walshe et al., 2014) increase the opportunity to detect performance issues. In reality, the regulator's means and decisions are shaped by austerity and demands to ease the regulatory burden.

Inspection mode: regulators can either pre-announce inspections or unexpectedly appear at the front door. The pre-announcement leaves time for the inspected organisation to plan and prepare.

Methods and tools: the complexity of healthcare, the difficulty to define healthcare quality and the need to evidence findings suggest employing a mix of methods and sources. This includes (statistical) data analysis, interviews with clinicians, managers, patients and relatives, surveys, observation and document review. Ideally, inspection tools should be consistent with current best practice and pre-tested (Dixon & Pearce, 2011; Sale, 2005; Tuijn, Robben, & Janssens, 2011). Since best practice tends to change over time, existing tools need to be regularly reviewed and new tools developed.

Regulatory credibility, which is largely dependent on the quality of the reviewers, lends authority to the regulatory regime and increases its effectiveness (Walshe & Phipps, 2013). Given the importance of relevant technical, regulatory and interpersonal competencies, many regulators assign external peer and lay reviewers to complement their in-house teams. Conversely, CQC's initial approach to employ generalist inspectors has been severely criticised as ineffective (Beaussier et al., 2015). Apart from the type and mix of skills, the regulator needs to allocate an adequate number of team members.

2.5.3 Post-inspection

The reviewed literature identified several components and mechanisms that regulators use after the inspection visit. The post-inspection activities are listed here in the typical sequence of their occurrence. They comprise (i) the provision of feedback to the regulated organisation, (ii) the reporting and publication of inspection findings, (iii) the preparing of improvement plans by the inspected organisation, (iv) the follow-up of the implementation of corrective actions by the regulator or another authorised body as well as (v) formal and informal enforcement of corrective actions.

(i) Feedback

Oral feedback at the debriefing summarises the inspection findings and typically highlights certain aspects. The feedback supposedly draws the attention of the audience to both, (i) good practice, which the regulator acknowledges and thus intends to reinforce, and (ii) compliance gaps, which the regulated organisation is expected to address by taking corrective actions and changing behaviour. The effectiveness of feedback is influenced by many factors, such as the source, format and duration (Veloski, Boex, Grasberger, Evans, & Wolfson, 2006), content and nature of the feedback (Hysong, 2009) and possibly accompanying interventions (Ivers et al., 2012; Vos et al., 2009).

(ii) Reporting and publication

The inspection report is potentially read by different groups, such as the regulated organisations, ministers, civil servants, local authorities, the media and the public (Day & Klein, 2004). As diverse as the audience are the pathways by which reports are believed to contribute to an effective inspection regime (Berwick et al. 2003; Hibbard et al. 2005; Hysong 2009; Raleigh & Foot 2010):

- The inspected organisation is expected to use the information about compliance gaps and specific recommendations for performance improvement to take corrective actions. The motivation either stems from the intrinsic desire to provide high quality services (change pathway) or the fear of damage to reputation (reputation pathway) and/or market share (selection pathway).
- The published report might also animate competitors to pre-emptively improve compliance/performance.
- Publicised inspection results hypothetically influence the decisions of potential customers, who have timely access to relevant information, interpret it correctly and have a choice of different providers.

- Other stakeholders such as local and national authorities, activists and media may add pressure on incompliant providers or offer support to improve performance.

While these pathways work in theory, many contextual factors and variables may increase or decrease the contribution of reporting to regulatory effectiveness. Amongst those are the presentation and readability of the reports (different target groups have different requirements), motivation and capability of the regulated organisation, triangulation of findings and explicitness of recommended actions (Benson et al., 2004; Day & Klein, 2004). Ideally, the information should be timely, accurately portray the situation, be meaningful to the reader and preferably be comparative (Marshall & McLoughlin, 2010; Nash & Goldfarb, 2006; Shekelle, Lim, Mattke, & Damberg, 2008).

(iii) Action plans

Improvement plans are developed in response to the identified compliance gaps, operationalising the required actions and recommendations in terms of detailed activities, time-scheduling and allocation of responsibilities and resources. This will facilitate subsequent monitoring and evaluation.

Previous research has identified weaknesses in action plans, which were attributed to insufficient planning capacity amongst the regulated organisations (Benson et al., 2004; Day & Klein, 2004).

(iv) Follow-up

Postulating rational behaviour, healthcare providers will adhere to the agreed action plan more readily, if they know that implementation is externally monitored and non-implementation will lead to negative consequences.

The effectiveness of regulatory regimes can be undermined by different practices in how to monitor and evaluate the implementation of action plans (Hovlid et al., 2015) as well as a discontinuity in the oversight, i.e. when the regulator's responsibility ends with the action plan (Day & Klein, 2004).

(v) Formal and informal enforcement

Formal enforcement embraces a range of activities such as issuing warning letters, imposing a ban on new admissions and suspending or revoking the registration. Single regulators can increase their scope of power by networking with other review bodies, governmental and local authorities, advocacy groups and the media (Braithwaite, 2008; Healy, 2016). Moreover, they can use informal means, such as persuasion, negotiation and threats. According to the responsive regulation approach, regulators should start at the bottom of the regulatory pyramid and depending on the response navigate up and

down (Braithwaite & Hong, 2015; Nielsen & Parker, 2009). This entails analysing the contextual factors and reasons for non-compliance as well as the effectiveness of the various enforcement approaches (Walshe & Boyd, 2007).

Capable, rationally acting healthcare organisations can be expected to comply with regulatory standards or make necessary changes to achieve compliance, if otherwise they have to fear negative consequences that surpass the potential benefit of non-compliance (Kagan & Scholz, 1984). This deterrence mechanism will be reinforced by salient examples of other regulated organisations that had to pay a ‘high price’ for non-compliance. The regulator can harness the fear by threatening to take punitive enforcement actions, including repetitive inspections, if the non-compliant healthcare provider does not rectify the issue (Walshe & Boyd, 2007).

Severe punishment and/or the loss of reputation can teach the non-compliant organisation itself the lesson to avoid non-compliant behaviour in future (Walshe & Boyd 2007). This mechanism relies on the (i) capability of the regulated organisation to change and (ii) the belief that non-compliance will be detected and punished in future. The publication of the non-compliance report and enforcement actions may increase the ‘naming and shaming’ effect for the organisation and serve as a deterrent for others. This mechanism might lose its effect, if non-compliance becomes a wide-spread, seemingly accepted phenomenon and regulators find it impossible to enforce completely (Beaussier et al., 2015). Moreover, a quasi-monopolistic NHS organisation will hardly be deterred by a warning (Beaussier et al., 2015) or the non-credible threat to be closed down (Baldwin & Black, 2008; Braithwaite, 2008). Individual managers might however fear to lose their jobs, when an NHS trust is put under special measures. Though, the replacement of senior managers will not automatically lead to immediate improvement (Rose, 2015).

2.6 Conclusions

This chapter briefly described how the theoretical and empirical literature on regulation in general and healthcare inspections in particular moved from description to a more refined analysis of change mechanisms and contextual factors. While the academic literature body is growing, the number of evaluation studies on inspection regimes is still limited. No scientific literature was found that explores HIW’s acute hospital inspection regimes.

The sparse evidence of regulatory effectiveness signals the inherent difficulties in evaluating organisational performance and inspection regimes under real-world conditions. The fundamental challenges and real-world complexity call for caution: ‘Conclusive evidence of effectiveness may never be possible’ (Øvretveit & Gustafson,

2002, p. 274). A difficulty, which academic literature tends to neglect, is the variability of inspection regimes. Due to the heterogeneity of regulatory tasks and responses, inspection regimes rarely follow a standardised format. Moreover, they change over time due to the necessity to adapt to new challenges. Since an inspection regime consists of different components, it is essential to examine the various mechanisms of what works, when and how in the regulatory context.

Most of the reviewed theoretical frameworks comprise the three core elements of the quality improvement cycle: direction, detection and enforcement. The frameworks as such do not solve the difficulties of inconsistent information that the researcher is confronted with. The framework recently applied in Walshe and colleagues' evaluation of CQC's hospital inspections provides analytical guidance by comparing the assumptions about change mechanisms with the implemented actions, results and impact.

The next chapter will show how the information gathered through this literature review was translated into the development of the research questions and methodology.

3 Methodology

This chapter describes the approach and the activities that were undertaken to ensure a thorough and systematic inquiry to answer the research questions. It explains the rationale for the inquiry and the choice of the particular evaluation approach, strategy and methods. The further sections lay out the stages of the research process and the specific activities to gather, analyse and interpret the empirical data, including ethical issues. The last section discusses the challenges related to this research.

3.1 Realistic Evaluation

Over many years, the proponents and opponents of different research paradigms engaged in a fundamental debate, which resembled more a war (Lincoln & Guba, 1985) than a fruitful dialogue (Guba, 1990). To the present author, a debate on what constitutes the right belief appears rather missionary, at best academic, but futile. In her opinion, the alleged incompatibility between quantitative and qualitative approaches (Flick, 2011; Lincoln & Guba, 1985) is a deadlock and a missed opportunity. She fully agrees with Patton (2011, p. 13), who pragmatically notes that there are 'no logical reasons' why qualitative and quantitative data could not be used together.

Nowadays, many writers portray the various research paradigms and approaches not as dichotomies, but as a continuum (Sale & Brazil 2002; Johnson & Onwuegbuzie 2004; Creswell 2009) which spreads between two poles:

- A (post)positivist epistemology at one end, which is associated with an objectivist ontology and axiology and advocates purely quantitative research. This entails measuring quantifiable data and calculating statistical correlations - aiming to establish causal relationships.
- A relativist/constructionist ontology at the other end, which is associated with an interpretivist epistemology and subjectivist axiology and advocates purely qualitative research. This entails collecting and interpreting qualitative information - aiming to investigate a social phenomenon in more depth and thus develop a better understanding.

The realist paradigm stands somewhere in the middle of this continuum, sharing the positivist ontology about an objective, external reality, yet acknowledging the inherent limitations of human beings to objectively comprehend social phenomena. Realists, such as the author of this thesis, recognise that research and researchers are affected by values, worldviews and cultural experiences. What primarily counts for a realist researcher is a 'scientific attitude', which entails systematic, sceptical and ethical

research, aiming to establish and/or test theories to explain the real world (Robson, 2011, p. 18).

This research adheres to a subtle realist assumption (Hammersley, 1992) that the reality of inspections exists independent from the interpretations of the various stakeholders. By addressing hospital regulation and inspection from different viewpoints, the study aimed to 'approximate' (Denzin & Lincoln 2003, p.14, referring to Guba) and ideally capture the complex reality with its inherent mechanisms that occur in social, political and other contexts.

This research seeks to apply the realistic philosophy to an evaluation. Evaluation science has increasingly become theory-oriented, employing qualitative, quantitative or mixed methods on the basis of which best suits the specific purpose (Donaldson, 2007). Realist evaluation as 'a relatively recent current in theory-oriented evaluation' (Vaessen & Leeuw 2009a, p.147) offers a 'particularly promising approach' (2009b, p. 13).

Realist evaluation and research is concerned with revealing the mechanisms (M) which generate certain regularities (R) in a corresponding context (C). Pawson and Tilley (1997, p. 71) express this in the formula *regularity = mechanism + context*. In the social world, such regularities typically relate to patterns of behaviour which constitute social phenomena, changes, specific events or programme outcomes (O). Realist evaluation aims 'to find ways of identifying, articulating, testing and refining conjectured CMO configurations' (Pawson & Tilley, 1997, p. 74). As the underlying causal mechanisms are often hidden (Pawson & Tilley 1997; Pawson 2002; Tilley 2009) initial propositions need to be developed and the particular context identified which make the mechanism 'contingent and conditional' (Pawson & Tilley, 1997, p. 71).

The choice of realist evaluation was prompted by several factors. The approach informed and seems appropriate to answer the research questions (viz. below). Hospital inspection regimes (the research subject) constitute real and observable events. Their nature resembles a governmental policy which is implemented like a programme; hence the choice of programme evaluation. Hospital regulation aims at influencing organisational behaviour (Walshe, 2003). Organisational behaviour does not occur on its own. In the case of UK hospitals, it results from collective and individual behaviour of hospital managers and staff, interacting with inspectors in the complex UK healthcare setting with dynamic changes.

Thus, the general underlying propositions for this thesis were:

- a. There is no single regulatory inspection regime that fits all purposes and hospitals equally. The regimes have comparative advantages and disadvantages.

- b. The diversity of regulatory objectives, regulated hospitals and other circumstances require a responsive approach, i.e. regimes that are specific to the contextual factors.
- c. The more the regulators are aware of the different context-mechanism-outcome configurations, the better arrangements they can make for effective regulation and inspection, provided they have the necessary resources, capability and motivation.

The distinction between the features of inspection regimes as strengths and weaknesses is a judgement which may not be equally shared by all stakeholders. With its general purpose to investigate the strengths and weaknesses, and thus effectiveness, the analysis of hospital inspection regimes applied by HIW constitutes a piece of evaluative research (Bowling, 2009; Patton, 2002). Besides its evaluative nature, this study also addressed contextual and diagnostic aspects (Ritchie & Spencer, 1994) and contains elements of formative and summative evaluation (Clarke & Dawson, 1999). Ideally, the findings and recommendations of this study will contribute to the growing body of prescriptive research, i.e. 'how regulation should be organized' (Baldwin et al., 2012, p. 40).

The research has not been primarily conceptualised as implementation evaluation, which would examine the difference between planned and actually conducted programme activities (Patton, 2002). Yet, such discrepancies are vital for the analysis and have therefore been studied. While the application of quantitative methods was initially taken into consideration, a predominantly qualitative approach appears more appropriate. This is due to the complexity of the regulatory environment, the change dynamics, the nature of the research questions and the lack or limited access to relevant quantitative data. This evaluation study does not endeavour to control any of the (partly interrelated) variables. Despite a general preference for quantitative research designs amongst (positivistic) scientists, an experimental design such as a randomised controlled trial would not be feasible for this evaluation. Moreover, several authors have critically commented on the practical challenges and inherent weaknesses of experimental black box designs in complex programme evaluations (Chen & Rossi 1987; Trochim 1989; Shadish 1992; Pawson & Tilley 1997; Stame 2004; Donaldson 2007; Yin 2009).

In line with Pawson and Tilley's realist programme evaluation (1997) the thesis drew on existing quantitative and qualitative information and generated primary (qualitative) data to answer the research questions. Explicit programme theories have been generated (viz. 2.5 Change mechanisms), tested and refined in an iterative process, which substantially relied on (qualitative) interviews and documentary evidence. Inspection

reports were used as secondary data sources to inform the research process. The use of qualitative methods also reflects the fact that HIW's inspections reports almost exclusively consist of qualitative information, since the practice of scoring hospital performance was abandoned in the late 2000s.

The holistic approach of a case study, which was chosen for this study, allowed more depth into the issue under consideration than alternative research designs with a single data-collection method (Anderson & Arsenault 1998; Bowling 2009). Despite the 'traditional prejudices against the case study' Yin (2009, p. 14) plausibly argues for the advantageousness of case study inquiry as a robust evaluation research strategy, when applied rigorously. The case study is particularly suitable 'to explain presumed causal links in real-life interventions that are too complex for surveys or experimental strategies' (Yin, 2009, p. 19). Moreover, the richness and diversity of data at the selected hospital sites are instrumental in identifying the contextual factors which trigger the causal mechanisms and influence the outcomes of hospital inspections. Theory-oriented evaluation research literature comprises numerous examples of credible case evaluations (Yin 1992; Pawson 2002; Vaessen & F. Leeuw 2009a; Posavac 2010).

3.2 The research design

After carefully reading the relevant literature, motivated by the researcher's interest and informed by her realist stance and the theoretical framework, the initial research ideas were translated into a set of research questions and a corresponding study design. The thesis investigated the phenomenon of healthcare regulation with the primary aim to answer the question:

What are the strengths and weaknesses of the inspection regimes that HIW has implemented in acute care hospitals in Wales?

The specific research questions were:

- I. How far have the inspection regimes been implemented and what specific problems have been encountered during implementation?
- II. Which elements and mechanisms have shown to be effective in which specific setting?
- III. What modifications to the regimes are likely to improve their effectiveness in a particular setting?

While the main research question is apparently descriptive, it implies a causal inquiry of 'what works, how and why' as the specific questions show. The formulation of the research question was kept deliberately open. Strengths and weaknesses do not refer to outputs or outcomes only. They concern any aspect, including inputs, implementation

issues and goals, and particular elements of the inspection regimes which work well in their context.

The study was based in Wales and focused on the Healthcare Inspectorate Wales (HIW). HIW was chosen for various reasons:

- HIW's inspection regimes have not been the subject of previous research, presumably due to HIW's small size and untainted reputation.
- Unlike its counterparts in England, HIW did not undergo severe reorganisations, which would have obstructed the research. Conversely, HIW's inspection regimes evolved over time and involve external peer reviewers and lay reviewers; a practice which CQC subsequently introduced.
- After devolution, Wales followed its own path towards organising healthcare and healthcare regulation, which promises interesting findings.
- On its website, HIW publishes inspection reports and other information which can inform the research as secondary data in English language.

The researcher contacted HIW at an early stage to ensure HIW's participation. In spring 2014, HIW's contact person arranged a formal agreement between HIW and the researcher, which stipulated the conditions for the evaluation research (viz. Appendix 1 Agreement between HIW and the researcher). HIW supported the researcher by arranging interviews with its staff and providing access to certain documents. Due to confidentiality, HIW did not facilitate contacts between its peer or lay reviewers and the researcher.

The selection of the healthcare organisations did not follow an experimental sampling logic, but was more a 'matter of discretionary, judgemental choice' (Yin, 2009, p. 56). The original plan to choose hospital sites as units of analysis based on their inspection results and the intended categorisation of hospitals was abandoned, after it became clear that this strategy would not work for a variety of reasons:

- Firstly, a categorisation of hospitals into excellent, average and poor performers was not supported by HIW ongoing inspection regimes.
- Secondly, the researcher had no information about the inspection sites before the inspection reports were published.
- Thirdly, most participants referred in the interviews to several inspections at various inspection sites and highlighted the diversity of healthcare quality across different wards within the same hospital. Had the researcher restricted the interviews to one particular inspection and site, this would have resulted in a loss of valuable information.

Instead, the researcher decided to recruit participants from all NHS and independent healthcare organisations in Wales, which operate acute, non-mental healthcare hospitals. It was deemed that this strategy would help to

1. Cover a wide spectrum of healthcare organisations, hospitals and inspection sites, ranging from excellent to sub-average performers,
2. Capture a variety of experiences with effective and less effective hospital inspections,
3. Identify similar or dissimilar context-mechanism-outcome patterns across the different healthcare organisations.

All relevant NHS healthcare organisations, i.e. seven Local Health Boards (LHBs) and one trust, participated in the study. Unexpectedly, each NHS organisation had different procedures and forms in place for the approval of the evaluation research. In some cases, the respective research and development departments provided additional guidance concerning the recruitment of research participants.

All independent healthcare organisations that were approached initially agreed to participate in the study, but two withdrew before an interview took place. In addition, the researcher conducted interviews with a representative body of the independent healthcare organisations in Wales.

Table 3 presents the composition of healthcare organisations that participated in the study.

TABLE 3 PARTICIPATING HEALTHCARE ORGANISATIONS

NHS	Independent healthcare
7 Local health boards (LHBs)	4 independent healthcare organisations
1 Trust	1 organisation representing the independent healthcare organisations

As the stakeholders play an important, interactive role in making implicit programme theory explicit and testable (Pawson & Tilley 1997; Donaldson 2007), the invitation of the most relevant stakeholders to the research process appeared crucial to its success. The identification of participant groups was informed by previous studies on healthcare regulation, particularly Benson and colleagues (2004) who in their case-study targeted the hospital chief executive, medical director, clinical governance lead, clinical lead for the reviewed clinical area, the review manager and assistant director.

The major criterion for the selection of participants for the study was their knowledge and experience in regulatory hospital inspections in Wales gained through active or passive involvement in HIW's hospital inspections or particular elements of them. This comprised

- Current and previous HIW managers;
- Current and previous HIW peer reviewers, including three professionals, who participated in the Trusted-to-care spot-checks in 2014, which were organised by the Welsh government;
- Current and previous managers of NHS or independent healthcare organisations in Wales, including LHB directors, hospital directors, divisional nurses and clinical leads.

Potential research participants were either identified directly by the researcher or recommended by the respective healthcare organisation or other research participants (snowballing). The researcher accessed publicly available directories and information such as websites of healthcare organisations, publications concerning the inquiry into the work of Healthcare Inspectorate Wales (Health and Social Care Committee, 2014) and the review of healthcare standards (Welsh Government, 2014). The information helped to identify individuals who due to their managerial role were likely to have experienced HIW inspections. These managers were approached by email and given further information about the study and its purpose. Some participants were recruited during two consultation workshops related to the independent inquiry into HIW by the Welsh government (Marks, 2014). Other participants were recruited thanks to recommendations made by research participants or healthcare managers, who did not participate in the study. Typically, the interviews were prearranged via email, but in several instances date and location were agreed on the telephone. An information sheet (viz. Appendix 2 Information leaflet) and the consent form (viz. Appendix 3 Consent form) were sent by email to each participant prior to the interview. Written informed consent was sought before the interview started.

The semi-structured interviews were piloted in spring 2014 aiming to learn about the practical difficulties of conducting a case study in a sensitive and topical area as hospital regulation. Seven pilot face-to-face interviews were conducted: two with research participants from the NHS and five with participants from the independent health sector. The piloting was instrumental in applying and modifying the evaluation strategy, techniques and interview guide. The interview guide contained a set of pre-formulated questions which were structured according to the pre-identified components of the inspection regime. During the piloting, the structure of the interview guide was slightly modified, several questions were reformulated as open-ended questions and a section

on 'self-assessments' was added. The latter reflected the relevance that interviewees attributed to the self-assessments which HIW had employed in previous inspection regimes (viz. Appendix 4 Interview guide).

Altogether, the researcher approached 67 healthcare managers and interviewed 46 participants, the majority of whom from the NHS.

TABLE 4 COMPOSITION OF RESEARCH PARTICIPANTS

Participant Groups	HIW managers	NHS managers	Independent managers	Total number of participants
Number of participants	7	31	8	46

Table 4 shows the number of participants according to their place of employment at the time of the interviews. Several interviewees fell into more than one category and had previous experience in other roles, such as

- HIW managers who previously worked as NHS managers or vice versa;
- NHS managers, who performed temporary roles as HIW peer reviewers;
- Independent hospital managers, who had previously worked in the NHS and vice versa.

Eight participants had either current or previous working experience as HIW managers, 34 participants had current or previous experience as NHS managers and nine had current or previous experience in managing independent hospitals. Amongst the healthcare managers were four individuals, who were trained by HIW as Cancer-peer-reviewers, and seven HIW peer reviewers, three of whom had actively been engaged in the Trusted-to-care spot-checks. All interviewees were senior managers with more than 10 years professional experience. Many participants had additional active or passive experience in other inspection regimes, including those conducted by CQC.

The researcher had initially considered the participation of lay reviewers but was unable to gain access. Neither patients nor professional associations or unions were directly involved in the study. This approach may be a source of bias but seemed the only feasible solution given the restricted time and resources.

The initial attempt to recruit equal numbers of research participants with a (i) medical, (ii) nursing and (iii) non-clinical background was impractical. Despite the efforts to equally balance the composition of participants, 67 percent were trained nurses and only 15 percent of the participants were males. The latter can be explained by the large proportion of females within the nursing profession.

One participant was interviewed online through skype and 45 participants were interviewed face-to-face on site. Face-to-face interviews were preferred due to the more natural conversation atmosphere and the opportunity this created for the researcher to visit the respective healthcare organisation and gather additional visual evidence. Apart from one joint interview, which was arranged at the request of the two interviewees, the interviews were conducted confidentially on a one-to-one basis. One HIW manager was re-approached for two follow-up interviews on skype, because this was logistic-wise more convenient. Previous studies faced similar obstacles in arranging face-to-face interviews (Benson et al., 2004) or entirely relied on telephone interviews (OPM referred to in Flodgren et al. 2011).

The overwhelming majority of interviews took place in 2014. Three interviews with healthcare managers and two follow-up interviews with one HIW manager were conducted in the second half of 2015.

Due to the iterative nature of the realist evaluation process the actual interviews often resembled an informed dialogue, which included clarification and probing questions. These were instrumental in refining the programme theory and answering the particular research questions concerning the strengths, weaknesses, mechanisms and contextual factors of hospital inspections.

The interviews were audio-recorded with the explicit permission of the participants and hand-written notes were made to capture strategic statements of participants and ideas of the researcher arising during and after the interviews. The field notes also contained information about the setting and the interviewee. Each interview was transcribed and electronically saved. The content of interviews was analysed immediately to inform the analysis and further interviews. The interviews provided access to additional materials, which were beneficial for corroborating the interview data.

3.3 Analysis

As explained above, data collection and data analysis are interlinked in realist evaluation. Interpretation of context-mechanism-outcome configurations and the related strengths and weaknesses of hospital regulatory regimes were developed gradually and in close cooperation with the research participants (Manzano, 2016). While data analysis techniques and software can facilitate the data analysis and visualisation, they are no substitute for the intellectual process of interpretation, which relies on familiarising with and reflecting on the collected evidence. The study employed several strategies and techniques to support the data analysis (Yin, 2009). The latter include pattern matching, the development of logical models and cross-case synthesis. Wherever available the

study used both, quantitative and qualitative data, ideally from different sources (triangulation) to develop, test and refine its preliminary propositions.

The qualitative information, i.e. interview transcripts and other documents such as inspection reports, was analysed according to the framework analysis method (Ritchie & Spencer 1994; Huberman 1994; Miles & Spencer et al. 2003; Green & Thorogood 2004; Lacey & Luff 2009). This data analysis method is considered a suitable tool in qualitative research to assess policies and procedures that have 'specific questions, a limited timeframe, a pre-designed sample and a priori issues' (Thomson, Taber, Lally, & Kazandjian, 2004). The analysis entailed the activities of (i) Familiarisation, (ii) Developing a thematic framework, (iii) Segmentation and coding, (iv) Summarising and synthesising, (v) Comparing and contrasting as well as (vi) Interpreting and reviewing.

(i) Familiarisation

The researcher familiarised herself with the interview materials by transcribing the recordings, repeated reading of and reflecting on interview transcripts, field notes and other documents as well as producing memos and summaries. The researcher transcribed nine of the interviews and carefully reviewed, proof-read and corrected, when necessary, the remaining transcriptions that were produced by a contracted external transcriber, who applied the same transcription instructions (viz. Appendix 5 Transcription instructions). The transcriber undertook to ensure absolute confidentiality on the content of the digital recordings and transcripts and to comply with the respective instructions stipulated in the agreement (viz. Appendix 6 Agreement between the researcher and the transcriber).

(ii) Developing a thematic framework

A thematic framework was developed during the desk-study based on the insights gained through the preceding literature review (Boyne et al., 2002; Walshe & Phipps, 2013) and was refined during the piloting and throughout the analysis of interviews (viz. Table 5 Thematic framework structure, viz. Appendix 7 Coding framework). The framework was instrumental in structuring the interview guide and provided the codes and structure for the further analysis of materials.

TABLE 5 THEMATIC FRAMEWORK STRUCTURE

Headings	Major elements / categories
Context and background	<ul style="list-style-type: none"> • UK and Wales • Failings in healthcare • Ownership (NHS - Independent sector) • Size and type of hospitals • Variation in care quality
Regulation and inspection	<ul style="list-style-type: none"> • HIW's remit, purpose and general approach • HIW review and reorganisation • Other review bodies (including CQC)
Pre-inspection process and elements	<ul style="list-style-type: none"> • Healthcare standards • Registration • Self-assessments • Selection of inspection sites and pre-inspection information
Inspection process and elements	<ul style="list-style-type: none"> • Inspection themes and topics • Frequency, timing and duration • Inspection mode (unannounced and announced) • Inspection methods, process and tools • Inspection team
Post-inspection process and elements	<ul style="list-style-type: none"> • Oral feedback • Immediate actions • Reporting and publication • Action plans • Follow-up • Enforcement • Impact

(iii) Segmentation and coding

The interview transcripts were analysed according to the thematic framework (viz. Appendix 7 Coding framework and Appendix 8 Example of coded interview transcript), which included identifying and attributing themes to certain pieces of the interviews and written documents (coding). For the coding and analysis, the qualitative analysis software MAXQDA was initially employed, but abandoned as it did not seem to provide added value. Mendeley software was used to organise the transcripts, the reviewed literature and any other documentary evidence, including inspection reports and websites.

(iv) Summarising and synthesising

The data were summarised, categorised and synthesised in a systematic way. The headings, categories and subcategories from the thematic framework were used to structure and present the data. Three master documents were produced, which included summarised findings and relevant quotes, structured according to the thematic framework (viz. Table 5):

- The programme theory and implementation of HIW's hospital inspection regime from HIW's perspective
- HIW's hospital inspection regime from the perspective of healthcare managers (based on interviews conducted between March and November 2014)
- Recent changes in HIW's hospital inspection regime from the perspective of healthcare managers (based on interviews conducted in September – December 2015)

(v) Comparing and contrasting

Next, an analytical document was produced for each major element, which summarised the presumed programme theory/logic and contrasted this with the findings from the interviews and documents concerning the implementation of the hospital regime. Context-mechanism-outcome configurations as well as the perceived strengths of inspections were compared across the materials/participants. Differences and similarities were established by contrasting the interviews and documentary evidence concerning

- Healthcare organisations and hospitals, i.e. ownership (NHS – independent) and size (large LHBs, small hospitals and wards)
- HIW's different hospital regimes, i.e. Dignity and Essential Care Inspections, cleanliness spot-checks, general hospital inspections

To examine any possible biases and misinterpretations, comparisons were also drawn between the various interviewees (regarding their roles and perspectives) and between the various forms of data collection and sources. This included common patterns about what certain groups of participants and the reviewed literature perceived as mechanisms and strengths or weaknesses of regulatory inspections. Due to their different roles and exposure to hospital inspection regimes, interviewees contributed different perspectives and insights, which were often limited to particular elements of the hospital regimes. For example: in contrast to their colleagues in the independent sector, senior NHS managers were rarely interviewed during the inspections. Due to their double role in inspection regimes, peer reviewers typically provided very complex and detailed information concerning the inspection process and its effect on hospitals.

(vi) Interpretation and reviewing

Based on the above, the draft analyses and discussion chapters were produced. These included comparisons with findings from other hospital inspections regimes, i.e. Trusted-to-care spot-checks, Cancer-peer-reviews and CQC inspections. Preliminary

conclusions and assumptions were made based on the identified patterns and considered alternative interpretations. The draft summary report was shared with the 46 research participants and peers, including research supervisors, to seek their views, i.e. confirmation or alternative interpretations (member checking). Most of the eleven research participants who responded had no or only minor comments. At the suggestion of a participant, the researcher replaced the term 'informant' with 'participant' or 'interviewee' and slightly modified the definition of 'independent hospital' in the glossary. Only two participants, both either current or previous senior HIW managers, provided more detailed feedback, particularly concerning chapter 4, Inspecting. Their comments often (i) contained additional information such as that HIW's intelligence strategy had recently been published on its website, (ii) emphasised particular aspects or view-points, for example that HIW's decision to recruit peer reviewers was not primarily economically-driven, (iii) or suggested deleting or adding words such as omitting the word 'trendy' regarding HIW's claim of a risk-based inspection approach.

The feedback was carefully studied and, if plausible, considered in the final version of the thesis. Some of the comments were, in agreement with the two participants, incorporated in the thesis as citations.

3.4 Ethical issues

This study was approved by the university's ethical-research-committee. NHS Wales finally classified the study as service evaluation, since it did not entail clinical research and no participants were exposed to any increased risks during the research process. Before interviewing, the participants were informed orally and in writing about the (i) aims and nature of the research, (ii) the voluntary nature of participation and participants' rights and (iii) researcher's contact details. The participants were asked for prior written consent. A flexible time schedule was offered to accommodate their availability. All participants were treated with respect and sensitivity.

Confidentiality and data protection included:

- collecting essential information, avoiding unnecessary (personal/sensitive) data
- audio-recording with prior consent of interviewees
- safe storage of confidential data. Electronic data were kept on an external hard-drive, inaccessible by internet and stored alongside hardcopies in a safe, inaccessible to outsiders.
- audio-materials will be sent to the participants upon their request and deleted on the researcher's computer after the research has been completed.

- Pseudonyms were used for individuals and no names of hospitals were mentioned in the research reports, to avoid any possible damage regarding the 'reputation' or 'public image'.

The study was exclusively funded by the researcher's own means, no third-party funds were received.

3.5 Challenges of the research design and implementation

Throughout the evaluation, the researcher faced numerous challenges, which included unforeseen occurrences. Firstly, the evaluation of CQC's new hospital inspection regime that was commissioned to a team lead by Kieran Walshe (2014) and CQC's decline of the researcher's request to volunteer in this evaluation meant that she had to abandon the original design of a multiple case study. The comparative multiple-case study design, which is commonly employed in evaluation research (Patton, 2002; Yin, 2009), would have potentially provided more variation and thus a better basis for pattern matching (Trochim, 1989), theoretical replication (Yin, 2009) and differentiation or specification of theory. However, the change in plan allowed the researcher to investigate HIW's inspection regimes more thoroughly.

Secondly, the scarce inspections of acute hospitals in Wales in 2013 and the delayed publication of inspection reports meant that the researcher had to change her initial plan to select healthcare organisations based on recent inspections. Waiting for the publications would have delayed the research process and resulted in less timely information. Instead, the researcher contacted all relevant NHS organisations and gathered information about former inspection regimes. While this change undermined the plan of evaluating a clearly defined case (i.e. one specific inspection regime), it allowed the researcher to identify different features and mechanisms across HIW's previous and current inspection regimes.

Thirdly, the inquiry of HIW effectiveness by the Welsh Assembly and the subsequent independent review (Marks, 2014) proved to be opportunities. The published evidence and reports helped to inform this research. The consultative workshops, which Ruth Marks invited the researcher to, gave her access to potential research participants.

Fourthly, the repeated re-nominations of HIW's contact persons due to the reorganisation and high turnover of HIW staff in 2013-14 delayed the start of the interviews. However, the formal agreement with HIW, which the new contact person insisted on, proved to be instrumental and the new contact person supportive.

Fifthly, the National Institute for Social Care and Health Research Permissions Coordinating Unit (NISCHR PCU)³ initially classified the evaluation study as clinical research, required the researcher to register the study online in the Integrated Research Application System (IRAS project code 162651) and requested her to undergo the 'Introduction to Good Clinical Practice' training. After many weeks of waiting, a change in contact persons, exchange of emails and phone calls and the intervention of a research manager of an NHS Local Health Board, NISCHR PCU reconsidered its initial judgement and finally classified the study as a 'service evaluation'. This episode delayed the research interviews and made the researcher realise how obstructive well-intended regulation can be, when interpreted without discretion and common sense.

Sixthly, in 2014, the Welsh Government organised independently from HIW Trusted-to-care spot-check, which most interviewees referred to. In two cases, the researcher noticed during the interview that the research participant had confused a Trusted-to-care spot-check with HIW's Dignity and Essential Care Inspection (DECI). Though this mistake was addressed and clarified during the interviews, it cannot be excluded that other participants confused between the two unwittingly. Nonetheless, the references made to the Trusted-to-care spot-checks allowed the researcher to make comparisons between the two regimes.

Seventhly, to capture the changes in HIW's inspection regimes during 2014 and 2015, the researcher conducted two further interviews with an HIW manager and three interviews with healthcare managers. The interviews also helped to test the findings of the preliminary analysis.

Apart from those unexpected circumstances, the researcher had to address some key issues related to the research subject and design. These included:

The challenges in measuring hospital performance and the effectiveness of inspection regimes (as discussed in section 2.3 Healthcare regulation). A comparison of categorised assessment results, similar to the scheme in CQC's pilot inspections (Walshe et al., 2014), would have facilitated a comparison over time and different regimes. However, HIW discontinued the previous practice of categorising assessments. Therefore, the study predominantly analysed process patterns, which is an appropriate technique to enhance construct validity (Trochim, 1989).

Due to the mostly retrospective nature of the study, a recall bias amongst the participants could not be excluded. The researcher always asked the participants at the beginning of

³ NISCHR PCU coordinates the process of gaining permissions for research in NHS organisations across Wales.

the interview to describe their most recent experience with an HIW inspection. Moreover, she tried whenever possible to triangulate the information.

Although the study found no major difficulties in recruiting healthcare managers with a nursing background, not all potential participants responded, and some interviews never materialised, being repeated rescheduled and cancelled. Particularly, invitations sent to medical directors remained unanswered or were rejected. Thus, a bias concerning the selection of participants, healthcare organisations and data (Arthur & Nazroo, 2003) cannot be excluded.

The available timeframe and resources necessitated a restriction in the number of interviewees and prioritisation of participant groups. Given the small number of investigated healthcare organisations and hospital inspections, the thesis contains as Patton (2002, p. 584) eloquently expressed 'modest speculations on the likely applicability of the findings to other situations under similar, but not identical, conditions'. Further evaluation studies may be needed to confirm or refine its findings and the suggested modifications to the inspection regimes.

As a piece of qualitative evaluation research, the thesis does not claim to be externally replicable in a quantitative, experimental sense. The data collection and data analyses procedures in this study have been systematically conducted and documented to allow other investigators to repeat the operations and come to the same conclusions (Yin, 2009). However, the interview transcripts have not been enclosed in the final thesis to ensure confidentiality.

Although the researcher received intellectual and moral support from her academic and practice-based supervisors, the primary responsibility for the research is hers. A multi-disciplinary research team would most likely have offered 'a more comprehensive perspective' and thus may have come to slightly different interpretations (Rossman & Wilson, 1994).

It cannot be excluded that the researcher influenced the research findings directly or indirectly by her personality, gender (female), cultural (German), professional and educational background (MBA in hospital management) and language skills (non-native English speaker).

Her role as independent, foreign researcher, neither employed by an inspecting body nor the hospitals, placed her in an independent position, which potentially created trust and credibility amongst the various stakeholders. Research from inside through for example participant observation and with insider knowledge may have yielded slightly different data and interpretations. However, the confidentiality assured, and the rapport

established between the researcher and the interviewees provided the opportunity for expressing their views on the inspections that otherwise (i.e. through a document review only) would have remained unexpressed. Moreover, documentary and verbal evidence (interviews) from multiple sources have been used to establish a plausible chain of evidence. The comments research participants made on the draft study reports have been carefully reviewed and considered in the final version of the study report. All these tactics aim at enhancing construct validity (Yin, 2009).

3.6 Conclusion

This chapter has described how the realist evaluation approach guided the study design and the actual research process. Theory-driven programme evaluation seems a particularly suitable approach for the investigation of the regulatory hospital inspections, which occur in a complex and dynamic 'real world' environment. Due to the combination of regulatory theory and practice it offers 'some important lessons in how to make regulation work better' (Walshe, 2003, p. 238). Conversely, an experimental strategy would neither have been feasible nor recommendable under field conditions.

The change in circumstances necessitated deviations from the original research plan and thus required a balanced decision between flexibility and rigor. The strength of this study lies predominantly in the iterative discussions with research participants from different stakeholder groups and the use of other sources of evidence to confirm or falsify specific features of the programme/change theories and contrast the theory with actual implementation. Yet, certain biases and discrepancies in judgement are likely to remain due to the nature of this social science research.

The following chapters will present the findings concerning the strengths and weaknesses of HIW's hospital inspection regimes and its different components based on the document review and interviews with the various participant groups – starting with the Inspectorate itself.

Part II. Hospital inspections – HIW's perspective and the hospital managers' views

The second part of the thesis contains two chapters, which comprise the findings from the document review and the interviews with research participants. Chapter four presents HIW's hospital inspections from the perspective of the inspectorate, chapter five presents the views of the inspected healthcare organisations.

The structure of the chapters follows the thematic framework (viz. chapter 3 Methodology):

- The context, which describes the events and environment in which HIW's inspections take place
- HIW's general approach, which outlines the thematic focus, purpose and principles of HIW's inspection regimes
- Pre-inspection process, which includes the (i) healthcare standards, (ii) registration, (iii) self-assessments and (iv) selection of inspection sites
- On-site inspection, which comprises the (i) frequency, duration and depth, (ii) inspection mode, (iii) methods, process and tools as well as (iv) the inspection team
- Post-inspection process, which describes the (i) immediate feedback, (ii) reporting, (iii) action plans, (iv) follow-up and (v) enforcement
- Perceived impact of HIW inspections.

For the sake of confidentiality and readability, no distinction is made in the text between male and female participants, instead the terms 'she' and 'her' are used coherently for both genders.

4 Inspecting

This chapter describes HIW and its hospital inspection regimes from the perspective of the inspectorate, relying on official documents and interviews with HIW participants. As explained in the methodology chapter above, this comprises eight interviews in 2014 and 2015 with people who had current or previous working experience at the inspectorate and statements by eleven peer reviewers when made from an ‘inspecting’ perspective. The first section set the scene for the analysis of the three process stages. The latter sections describe how the inspections are supposed to be conducted, explore the nature of the problems which occurred during implementation, consider which elements and mechanisms worked or did not, and summarise the changes that HIW participants recommended to increase effectiveness.

4.1 Development and context of HIW’s inspection regimes

Wales is a small country with 3.17 million inhabitants (“Population of Wales 2016 [online],” 2016), 38 NHS hospitals with acute care functions and 31 community hospitals⁴, which comprise approximately 600 wards or areas to be inspected, as well as seven acute independent hospitals (Marks, 2014; NHS Wales, 2016). Since 2009, NHS Wales has been structured into three trusts and seven Local Health Boards (LHBs), which in contrast to England are responsible for both, commissioning and providing healthcare (Longley, Riley, Davies, & Hernández-Quevedo, 2012).

According to HIW participants, the small size of Wales and the few stakeholders facilitate HIW’s work regarding networking, exchanging soft intelligence as well as identifying concerns and trends. Review bodies in Wales have a history of cooperation, which is manifested through a joint website (Healthcare Inspectorate Wales, 2013b), concordats (Welsh Assembly Government, 2005a), joint reviews (Wales Audit Office & Healthcare Inspectorate Wales, 2013) and health summits.

HIW was established in 2004 as a governmental organisation, inheriting the functions from the Commission for Health Improvement (Hutt, 2004). Over the years, its functions expanded, including independent healthcare regulation, statutory supervision of midwives and clinical reviews of deaths in prison. As a regulatory body HIW’s role has been to provide ‘assurance about the efficiency, quality and safety in the absence of competition’ (Care & Social Services Inspectorate Wales, Estyn, HIW, & Wales Audit Office, 2011, p. 4). Although HIW emphasises its professional independence, the overwhelming share of HIW’s revenues derives from the Welsh government.

⁴ Excluding specialised mental health hospitals.

Initially, HIW (2007a) reviewed healthcare organisations against the whole range of healthcare standards (and still does in the independent sector). HIW's inspection regimes evolved in response to external factors, such as failings in UK healthcare, new government policies or duties given to HIW, and to internal developments, such as inspection findings and suggestions made by peer reviewers.

Based on the experience that inspection regimes or particular elements become obsolete over time, either because they have achieved their goals, or they appeared to be not effective enough, HIW has kept modifying the inspection scope, themes and formats. HIW's initial comprehensive compliance reviews in the NHS were replaced by more thematically-targeted inspection regimes: the cleanliness spot-checks in the late 2000s and the Dignity and Essential Care Inspections (DECIs) in the 2010s. With its four domains, i.e. (i) patient focus, (ii) patient experience, (iii) staffing, management and leadership and (iv) quality and safety, DECIs responded to the issues of poor care found at Mid Staffordshire in England and became HIW's major inspection regime for acute hospitals during the early 2010s. No disagreements concerning HIW's hospital inspection regimes were noted in the interviews with HIW managers.

DECI 'is our main acute hospital product' (IN18).

External and internal developments substantially weakened HIW's capacity and performance between 2012 and 2014 (Healthcare Inspectorate Wales, 2013c; Thomas, 2013), which HIW managers highlighted during the interviews. These included the budget cuts and early severance/retirement schemes, the relocation of HIW's head office, unfilled vacancies and the discontinuity in HIW's leadership. As a result, hardly any NHS hospital inspections were conducted in 2013 and several inspection reports remained unfinished. This undermined HIW's credibility as a regulator.

'I think we've had a hell of a job of work to do, in terms of rebuilding our credibility.' (IN14)

These problems and the public discourse on regulatory effectiveness in England triggered a public inquiry into the work of HIW (Health and Social Care Committee, 2014) and a subsequent review (Marks, 2014). At about the same time, an independent report on poor care within one NHS organisation in Wales was published (Andrews & Butler, 2014), which prompted the so-called Trusted-to-care spot-checks of seventy hospital wards in 2014. Due to HIW's capacity constraints, the Welsh government organised its spot-checks independently from HIW.

HIW resumed and intensified its activities during 2014 and launched a new hospital inspection regime in 2015 (Healthcare Inspectorate Wales, 2015o, 2015q), which reviews against the new health and care standards (NHS Wales, 2015b). While its focus

on patient experience, delivery of care, management and leadership resembles resembles the DECI, the new regime covers more hospital wards per inspection (Healthcare Inspectorate Wales, 2016a). With the publication of the summarised findings from its DECI (Healthcare Inspectorate Wales, 2015n) in 2015 and the new regime in 2016 (Healthcare Inspectorate Wales, 2016e), HIW (2007b) revived the previous practice of thematic reporting. Until 2016, when the government established a new steering group, HIW (2016f) had successfully supported the Cancer and Palliative care peer-review programmes through guidance, (lay) reviewers and organisational arrangements. HIW participants expressed their appreciation for the peer review scheme as a model, separate from HIW's regular inspection regimes.

“The peer review is a really, really good model. And I believe that professionally and clinically, because it absolutely transfers knowledge back, and across.”(IN22)

Differences have remained between HIW's inspection regimes for NHS and independent hospitals, though one HIW participant stated that the inspectorate might consider a unified inspection approach for all acute hospitals.

‘There are large similarities. But, where there are differences, I think we need to actually look at what is best, so that we can perhaps have one regime for both the independent and the NHS.’(IN22)

The same interviewee reflected on future changes to HIW's inspection regime, such as longer inspections covering the entire hospital or inspections along patient pathways. HIW has not documented the specific, underlying programme theories. While supporting the hospital inspection regimes, HIW managers sometimes articulated different views and suppositions as to how particular components of its inspection regimes work. HIW (2015f) defined four 'outcomes' and respective activities to achieve its purposes, which include providing assurance, promoting improvement, strengthening the voice of patients and influencing policy and standards. HIW have been using diverse regulatory means and informal approaches in striking the optimal balance to achieve its purpose(s) with its restricted financial means.

‘We would probably need to double our funding to do a good job. It's not a secret to say that our budget is about three million pounds. CQC's is about two hundred million.’ (IN18)

‘We can't argue, you know, there is a very constrained pot in Wales. Therefore, we have to be satisfied that everything that we spend the money on adds value’ (IN11).

Thereby, the inspectorate is aware that, no matter how effectively it sets its priorities, it cannot guarantee a 100 percent level of assurance.

'Because there's a cost attached to each of these things. 'Do you want us to give you a 100 percent guarantee that everything is always going to be OK? Forget it.' (IN6).

4.2 Pre-inspection

The findings presented below refer to those aspects or activities within HIW's inspection regimes that take place before the inspection team arrives at the hospital. This includes (i) healthcare standards, (ii) registration, (iii) self-assessments and (iv) selection of inspection sites. These elements are supposed to direct the healthcare organisations, establish a common understanding of the expected performance and inform HIW's decisions on inspection topics and criteria as well as inspection sites.

4.2.1 Healthcare standards

HIW reviews the healthcare services against 'a range of published standards, policies, guidance and regulations' (Healthcare Inspectorate Wales, 2014e). Amongst those were the 26 Doing-Well-Doing-Better (Welsh Assembly Government, 2010) for the NHS and the regulatory 25 National 'Minimum Standards for Independent Health Care Services' in Wales (Welsh Assembly Government, 2011) for the independent healthcare sector. In 2014, the Welsh government launched a review with the aim to unify the standards for all healthcare providers. The review aimed at integrating the 'Fundamentals of Care', which HIW predominantly employed in its Dignity and Essential Care Inspections (DECIs), and incorporating the recommendations from the Francis inquiry (Welsh Assembly Government, 2014). In order to develop ownership and thus 'guarantee the success of the revision of the standards', the Welsh Government (2014, p. 2) invited all relevant stakeholders. Although HIW was actively involved in the development and review of healthcare standards, it is not HIW's, but the government's role to set and endorse them.

'We clearly wanted them [the standards] to be owned by the government, because I felt, if they are owned by the government, actually they are more powerful.' (IN6)

The previous healthcare standards and the 'Fundamentals of care' explicitly aimed at quality improvement (Welsh Assembly Government, 2003, 2005b, 2010). The new, combined Health and Care Standards more modestly aspire to 'form the cornerstone of the overall quality assurance system within the NHS in Wales' (NHS Wales, 2015b, p. 5). Due to their intention to be applicable 'to all types and size of services regardless of their setting' (Welsh Assembly Government, 2010, p. 5), the Doing-Well-Doing-Better standards were generic. Though the new Health and Care Standards claim to be outcomes (NHS Wales, 2015b), they are not quantifiable, neither are the associated criteria (Malley, Holder, Dodgson, & Booth, 2014). Only a few of the standards and

criteria directly concern clinical effectiveness. Most standards relate to patient experience, human resources management or other managerial aspects. HIW managers recognised the difficulty to measure standards that derive from complex concepts such as dignity and respect⁵. While the standards are open to subjective judgement and bias, at the same time, they give the reviewers leeway for reasonable judgement.

'It works both ways. If you have rigid standards there is no room for manoeuvring for any party.'(IN13)

Referring to the more positive results and thus apparently more effective independent hospital inspections, some HIW participants considered the non-regulatory status of NHS healthcare standards a weakness in HIW's inspection regimes which required changing. According to another HIW participant, the positive results in independent hospital inspections seemed to be more related to the attitude and commitment of independent managers rather than the regulatory status of standards.

'Even though they've [independent hospital managers] met the standard, most of them [...] are not happy with the gold bar position. They want the platinum. They are never satisfied.' (IN13)

This and the fact that the commercial success of independent hospitals depends on good reputation and thus on positive assessment reports leave severe doubts that regulatory standards would automatically enhance compliance and quality in NHS hospitals.

4.2.2 Registration

In contrast to England, in Wales only independent healthcare providers are obliged to register and thereby demonstrate their compliance with the healthcare standards.

'[The purpose of the registration is] to make sure that the service they [independent hospitals] provide is safe for patients. That's the main reason. And there is a set of regulations and standards behind those regulations.' (IN12).

HIW interviewees admitted that there was no plausible explanation for this duality in treatment of NHS and independent healthcare providers other than the historic development.

'It's the same service at the end of the day. If you go to an NHS hospital to have an operation or if you go into a private hospital to have an operation.' (IN12)

⁵ Standard No.10 in the Doing-Well-Doing-Better Standards and the National Minimum Standards.

Independent hospitals are registered for certain conditions, such as a named manager or number of beds. HIW aims to support new healthcare providers with adequate guidance:

'We've got guidance on how to meet the standards. [...] And they pretty much take you through what you need to do to comply.' (IN12)

No evidence was gathered during the study that suggests a negative attitude or deterrent approach towards new acute healthcare providers. The respective HIW manager described the pre-registration process of an acute independent hospital as transparent and professional, emphasising the importance of appointing contact persons on each side.

'They had a link person, which was really important'. ... 'they kept us updated.' (IN13)

To improve the effectiveness of NHS inspections, some HIW participants advocated for the registration and licensing of all healthcare providers, similar to England. They argued that this would allow HIW to revoke the registration in case of a serious breach of standards or regulations by NHS organisations. Another HIW manager pointed to professional self-regulation and HIW's cooperation with professional bodies.

'Whilst NHS organisations aren't registered, every medical practitioner working in them needs to be registered with their relevant professional body. In this respect, HIW does have a route to raise concerns with these bodies if it identified risks to patients as a result of poor care and treatment and has routinely done so.' (IN14)

4.2.3 Self-assessments

In 2007, the Welsh government (2005b) introduced mandatory self-assessments against the healthcare standards, to be tested and validated by HIW as a 'third line of defence' (Dixon et al. 2012, p.15). The rationale of this approach was to shift the responsibility to the healthcare organisations and thus help to establish ownership and effective internal governance mechanisms. One former HIW manager described how HIW tested and challenged the self-assessments during the first few years.

'We disagreed with them [NHS organisations] quite often: "Your self-assessment here, we don't agree, because we don't think this evidence is convincing."' (IN6)

The participant further explained that, as time went on, the NHS organisations omitted updating the self-assessment, which she interpreted as 'bad habits' and laziness. Within the current framework, the LHBs and NHS trusts forward their annual self-assessment reports to the government. HIW is in charge of reviewing the governance and accountability module. The self-assessments inform the discussion between the

government, HIW and other review bodies at the healthcare summits (Healthcare Inspectorate Wales, 2015c). The LHBs usually receive some feedback after the summit.

To increase (self)regulatory effectiveness, one HIW interviewee proposed a legal obligation for NHS organisations to publish the self-assessments and thus expose them to public scrutiny.

'They should have published them [the self-assessments] on their own website, but again we couldn't make them' (IN6).

4.2.4 Selection of inspection sites and pre-inspection information

In the past, HIW usually inspected the wards within a hospital randomly, suggesting that this element of surprise (viz. 4.3.2 Inspection mode) may keep healthcare managers alert.

'One or a group of wards picked at random and you have to keep on testing your own thinking: These were actually picked up random, they didn't know we were coming.' (IN6)

In recent publications, HIW (2012c, 2014a, 2015t) has claimed to apply a proportionate, risk-based and intelligence-led approach in its hospital inspection regimes, which implies a purposeful selection of inspection sites based on prior data-analysis. The reviewed documents and interviews identified four rationales for HIW's inspections, which however partly deviate from the proportionate or risk-based inspection approach:

- i. Some inspections are conducted for the sake of visibility and alertness: even if there is no concrete evidence of concerns, omitting inspections for several years may risk incompliant behaviour.

'purposeful selection may include sites that the data tells us have not had an independent visit for a long time. I believe that 'blind spots' do themselves constitute risk' (IN11).

- ii. Independent hospitals expect annual inspections (Healthcare Inspectorate Wales, 2012c; Taber, 2013).
- iii. Healthcare services with inherently higher risk-levels due to the vulnerability of patients are intended to be regularly inspected (Healthcare Inspectorate Wales, 2015t).
- iv. Healthcare organisations with reported problems or poor indicators should undergo more inspections than others.

According to a former HIW manager, HIW became over time 'an intuitive and intelligent inspectorate', that monthly reviewed the available information, identified emerging trends and risk patterns and took informed decisions concerning the sites to be inspected. This

statement was qualified, if not contradicted by two newly appointed HIW managers, who maintained that until recently HIW did not have the necessary capability. Since 2013, HIW's ability to systematically analyse hospital data has increased after establishing a corporate intelligence team (Healthcare Inspectorate Wales, 2015c, 2015p) and enhancing the mechanisms to share and use intelligence (Healthcare Inspectorate Wales, 2016g, 2017a) The decision on which sites to inspect involves the intelligence team, the relationship manager for the respective Local Health Board (LHB) and the lead review manager.

'[The intelligence] team will produce pre-inspection evidence packs. And that will involve drawing on published data, non-published data, but also a lot of other intelligence sources.' (IN9)

HIW introduced the roles of relationship managers and lead review managers for every LHB to enhance the identification of trends at an early stage and the feedback of concerns to the respective healthcare organisation, the government and the Wales Audit Office and thus increase the effectiveness of its inspection regime.

HIW has access to data and information from different sources, including self-assessments, fundamentals of care audit reports and performance data, but also soft intelligence. Opinions amongst HIW participants differed concerning the extent to which data should inform the inspections and selection of inspection sites. For a purposeful selection of inspection sites, one HIW interviewee considered only a small set of six or seven key indicators as decisive and admitted that those do not always form a clear pattern.

'If we come up with a rank list of 10 wards, I wouldn't necessarily assume that they are absolutely accurate. What I might say is the ones that are close to the top are probably better than the ones that are close to the bottom.' (IN9)

Another HIW participant called for caution not to solely look at data that are seemingly of concern, due to the risk of framing the reviewers' minds.

'To what extent is an inspection truly independent, if you go in with preconceived ideas of what the issues might be?' and concluded 'we shouldn't be going in too far with our inspections, with having formed our judgement before we arrive.' (IN11)

One peer reviewer supported this argument by instancing the example of a Trusted-to-care spot-check, which found poor care despite wonderful data.

'It was interesting, because some of the worst areas that we found, had wonderful data. That's bit worrying, isn't it?' (IN38)

To prevent potential bias, the peer reviewer explained that she refused to see the available intelligence prior to a later HIW inspection. Typically, HIW shares the collated data and information in the pre-inspection meeting with the external reviewers, who, like in the above case, may not always wish to be influenced by prior knowledge.

Access to statistical data and soft intelligence, including complaints and sensitive information from hospital staff, patients and their relatives, reportedly allowed HIW to conjecture about hospital wards. Although, as HIW managers and reviewers conceded, the available information may not necessarily lead to firm conclusions, participants emphasised that similar or reoccurring problems within a hospital or LHB might indicate a systemic problem, which requires further investigation.

‘We got three wards, they all got problems with infection. That means that we have to make an inquiry about the whole.’ (IN6)

Regarding the organisational implications, HIW senior managers carefully examine and countercheck information before acting according to the ‘degrees of being worried’. While HIW’s access to relevant data and enhanced analytical capacity can potentially increase regulatory effectiveness, one HIW participant advised caution.

‘This is still a very small team that has to contend with a vast amount of data and other intelligence.’ (IN14)

4.3 On-site inspection

The findings presented below refer to the aspects and components which are relevant at the time when the hospital is inspected. This relates to the (i) frequency, duration and depth, (ii) inspection mode (iii) methods and tools as well as the (iv) inspection team. These factors are instrumental in detecting whether a hospital is compliant or not with the respective regulations and standards.

4.3.1 Frequency, duration and depth

During the inquiry in 2013, HIW’s new chief executive raised the question of a ‘minimum frequency of visits, for particular settings’ (Health and Social Care Committee, 2014, p. 21) and put annual or six-monthly inspections into acute hospitals up for discussion. HIW’s activity levels in 2012/13 and 2013/14 were undisputedly low and admittedly insufficient for HIW to provide confident assurance (Health and Social Care Committee, 2014).

‘We can only provide as much assurance as we can, based on the resources that we got to do it. So, we got to try and do as much as we can.’ (IN14)

The targeted fifty wards for the Dignity and Essential Care Inspections (DECI)⁶ in 2014/15 (Healthcare Inspectorate Wales, 2014f) were in comparison to the eight DECI (Healthcare Inspectorate Wales, 2014a) in 2013/14, a significant increase, but, as HIW managers admitted, still a small number.

HIW's decision to maximize coverage⁷ for the 2014/5 programme was driven by HIW's intention to demonstrate presence and operational capability. Most, but not all of the 52 DECI in 2014/15 were conducted over a period of two days each (Healthcare Inspectorate Wales, 2015n), two of them on weekend days (Healthcare Inspectorate Wales 2015h; 2015i). The eight NHS hospital inspections during 2015/16, though a comparatively low figure at first sight, covered 15 hospitals and 43 wards in total (Healthcare Inspectorate Wales, 2016a). HIW (2015s, p. 8), expected from this approach 'a more robust assessment of themes and issues', hoping to support learning and improvement. Admittedly, the larger number of sites per inspection was accompanied by a reduction in the depth of the inspections at each ward.

'We are trying to strike a balance between coverage and the kind of depth based on the resources that we have.' (IN14)

In the independent sector, HIW intends to pay at least one annual visit to each acute hospital. While in the 2000s HIW visited an independent hospital up to four times per year, in the early 2010s inspections became less frequent.

'If possible, we like to visit all seven, because of the risk work that they do. In terms of- No matter how good they are, the fact that you are dealing with general anaesthetics, you are dealing with minors, with surgery, always places you within the ample direct category.'
(IN13)

4.3.2 Inspection mode

HIW's current hospitals inspections are predominantly unannounced, in contrast to the announced reviews against standards in the mid-2000s and the governance reviews (Wales Audit Office & Healthcare Inspectorate Wales, 2013). Despite the general preference for unannounced inspections, HIW interviewees acknowledged that announcements can contribute to regulatory effectiveness. One participant referred to CQC's announced 'massive' inspections in 2013/14, which due to increased publicity and visibility had a positive, preventative effect on other healthcare providers, who feared to get caught and exposed, if they did not get their 'act together'. HIW participants considered announced inspections as particularly suitable to drive improvement.

⁶ 52 DECI including 6 follow-ups were conducted in 2014/15.

⁷ Coverage refers to the percentage of inspected hospitals out of the total number of hospitals.

'If we are here to make a difference and to drive improvement, and you announce the inspection, and the behaviour that you get from that is that someone says "Oh dear, someone's coming in six weeks' time. We better improve our- we better train people, we better update our policies, we better clean the ward, we better do X, Y, Z." I think that can be a good thing, because it achieves the same end result.'
(IN18)

Announced inspections seem the only option, as another HIW participant explained, for paediatric services in independent hospitals due to the need to obtain informed consent for the interviews with children. HIW participants deemed an unannounced mode most suitable and effective for testing healthcare organisations in aspects such as cleanliness or pursuing a reported case of poor care.

To prevent any information leaks, HIW informs the respective peer reviewers about the particular location only one day before the inspection.

'There is a culture of not wanting to tell anyone when you are going into an unannounced inspection, because you don't trust anyone to keep it quiet.' (IN18)

For the same reason, only two people knew the exact schedule and hospital wards of the unannounced Trusted-to-care spot-checks in 2014.

Though very rare and not necessarily revealed in HIW's inspection reports, some hospital inspections have been requested by the LHBs themselves. HIW also receives invitations to participate in the LHBs' internal inspection schemes, which it is reluctant to accept with regard to its scarce resources.

4.3.3 Inspection process, methods and tools

The preparation for a Dignity and Essential Care Inspection (DECI) starts a week prior to the inspection with HIW's review manager receiving pre-inspection intelligence from HIW's intelligence team and continues with a team meeting shortly before the inspection. On arrival at the hospital, HIW informs the key stakeholders about the unannounced inspection, introduces the team members and conducts the inspection, unless there are legitimate reasons not to enter a particular ward.

'You spent ten minutes when you go in, talking to whoever is in charge, or a quarter of an hour. Ask them to show you around, ask if there is somewhere where you shouldn't go, in case you got an infection, you know, or somebody in the last days of life, you know, it's not appropriate. And then, you say, you know, "I am going to speak to patients, staff, if there are relatives in the ward I am going to look at the patients' notes, the patients' forms and charts, and then I'll come back to you if I have any queries, and then I'll feedback to you before we leave".' (IN38)

Later, the team meets to discuss the findings, necessary corrective actions and the feedback for the subsequent debriefing with relevant professional and managerial staff.

The process of independent hospital inspections is not dissimilar to the above but appears to be well-established with clear individual responsibilities.

'We do the walk. [reviewer A] will look in every room and every cupboard and look at every document and he will go outside and look at the water chlorination tanks. [...] [reviewer B], myself and [reviewer C] will look at the documentation, [reviewer C] will very well start speaking, just sitting quietly observing, talking to staff without interfering with their work, checking with patients, relatives and visitors. Anytime they would like to have a little discussion or talk is up to them, and so we gather our picture, slow but sure in the first three hours. [...] We also arrange to meet at half past twelve, one o'clock, so we do debriefing amongst ourselves. It's really important, because it may inform the focus of our next stage of visit.' (IN13)

The Cancer-peer-review⁸ process differs in that the inspected service completes in advance of the announced visit an online self-assessment. The peer reviewers are given sufficient time to critically review the strengths and weaknesses, interview the service providers and scrutinise the service.

DECIIs employ various methods: (i) document review, (ii) interviews, (iii) surveys and (iv) observation.

- (i) Reviewed documents include written policies, patient documentation and quantitative data. Since data are compiled and analysed at HIW's head office prior to the DECI, the inspection team concentrates on gathering and reviewing complementary information at the site.
- (ii) HIW interviews patients, relatives and staff, which HIW aims to do without interfering. In NHS inspections, it is typically the lay reviewer's task to interview patients and relatives. According to several peer reviewers, patients, especially the elderly, appreciate narrative interviews. Structured interviews were said to discourage patients from sharing information, particularly when the interviewer mechanically asked questions or writes notes in the patients' presence. Recently, HIW also started interviewing senior managers from 'the Health Board' (Healthcare Inspectorate Wales, 2015h) or 'the directorate' (Healthcare Inspectorate Wales, 2015q).
- (iii) Surveys for patients, relatives and visitors were introduced in the course of 2014 (Healthcare Inspectorate Wales, 2014c). Though the tool has not been published,

⁸ The Cancer-peer-review programme had been supported until 2016 by HIW but was operated independently from HIW.

apparently the structured questionnaire allows patients to add comments and rate the care between 0 and 10 (Healthcare Inspectorate Wales, 2015k). The thematic report, which contains the patient experience questionnaire results (Healthcare Inspectorate Wales, 2015n), does not present any scores, but the percentages for each of the three answer categories⁹ for 18 pre-formulated statements. Although HIW (2015n) received over 330 completed patient experience questionnaires from the 2014-15 DECI, not all 46 DECI reports mention questionnaires. Later inspection reports in 2015 contain information about the results from self-administered staff questionnaires (Healthcare Inspectorate Wales, 2016c).

- (iv) During general walks, the team members scan the physical environment and observe how patients are processed. Sensory evidence such as an aroma of mould or urine is used to establish patterns and informs further assessment activities. Reviewers explained that they try to underpin the first impression with factual evidence and analyse these clues to identify patterns.

HIW's cleanliness spot-checks and DECI reports rely on comprehensive checklists. According to one HIW manager, the development of HIW's inspection tools is informed by recent research and clinical guidelines issued by recognised bodies such as the Royal College of Physicians. For its cleanliness spot-checks HIW (2014d) adapted the Infection control audit tool, developed by the Nurses Association (ICNA)¹⁰. According to two peer reviewers, HIW's first infection reviews in 2006/7 and the Dignity and respect spot-checks in 2009/10 did not initially employ tested inspection tools. The interviewees described how a small team of clinicians developed the tools for the DECI programme in 2011, piloted and adapted them subsequently. The basis for the tools were themes and topics that were extrapolated from official reports. At a later stage, the themes and findings were linked with corresponding healthcare standards.

'So that when health boards got reports back, they could say: "This is our evidence against these standards.".' (IN44)

The interviewed peer reviewers emphasised the need to regularly adapt the inspection tools with regard to new findings and events such as Mid Staffordshire. The peer reviewers described the development of effective inspection tools as a learning process and complained that existing tools were not often enough reviewed in the past. Conversely, new tools can initially cause disruption.

⁹ 'Agree', 'neither agree nor disagree' and 'disagree'.

¹⁰ Renamed in 2006: Infection Prevention Society (IPS).

'They were also using a new tool on that day, so they seemed to be kind of struggling with the new tool and... who was doing what, and they seemed a little disorganised' (IN19)

The tools, that HIW's cleanliness spot-checks and DECI's rely on, are according to peer reviewers each between twenty and thirty pages long and require about six hours per ward to be administered. Not surprisingly, some peer reviewers referred to the DECI inspection as repetitive paperwork.

'The paperwork for the [Trusted-to-care] spot-check was a lot better from the one for Inspectorate Wales, because it wasn't a lot of repetitive questions. [...] generally, with the spot-check, you could ask whatever question that you wanted, which I think the patients benefited from and the staff benefited from.' (IN41)

Although noting an improvement in HIW's 2014 inspections, one participant still saw a need for refining the tools, which she and reportedly many other reviewers fed back to HIW during a training and review meeting in 2014. Some participants contrasted HIW's comprehensive inspection tools with the simple prompt cards¹¹ that the Trusted-to-care review team chose, emphasising that the latter created a more pleasant interview atmosphere. The reviewers stated that they quickly internalised the topics and questions.

'With the prompt cards, once you get used what is on there, you are not juggling, looking at a piece of paper, then asking a question, because you already know what is on the prompt card after you have interviewed a couple of people.' (IN41)

Pointing to the trade-offs between elaborate checklists and prompt cards, an HIW manager explained:

'Prompt cards rely a lot on the professional judgement of the reviewer: this can mean that the judgements can be susceptible to the particular bias of a reviewer. It can also reduce the consistency of coverage.' (IN11)

Some HIW interviewees and various peer reviewers relativized the importance of tools, arguing that inspection tools can neither substitute human senses nor compensate for a lack of analytical skills. Therefore, they suggested a degree of flexibility and discretion in administering inspection tools.

'You have tools to guide you, tools do not judge you. Overreliance on tools and a checklist will very quickly lead to a path of no return as far as I'm concerned. You must have a knowledge based in skill. Often when we find breaches or disclosures made to us, you must have the ability to see where something is untold.' (IN13)

¹¹ Sheets with a heading and some orientating questions.

One HIW participant explained the weaknesses in CQC's previous inspection programmes with an overreliance on checklists, combined with infrequent visits and not-fit-for purpose inspectors.

While previously inspection methodologies and tools had been published on HIW's website (Cooper 2005; Jones 2005; Healthcare Inspectorate Wales 2006a; 2006b; 2008; 2009), the later DECI tools were not. The early DECI reports in 2012 contain a link to the assessment tool which, however, ceased to be valid. Although one HIW participant conceded that the publication of inspection tools would increase transparency, she worried about the cost for the required translation into Welsh.

Although HIW's (2017b) guide on NHS hospital inspections does not contain assessment tools, in a comment on the draft thesis, HIW stated that:

'Specific tools are not confidential and are available on request.'
(IN11)

4.3.4 Inspection team

Inspection teams should, as several HIW participants explained, comprise a mix of relevant competencies, including professional and interpersonal skills as well as knowledge of healthcare regulation and standards. Amongst the 50 staff members are 30 inspection and regulation staff¹². In addition to its permanent staff, HIW has a pool of about 200 external reviewers.

A typical DECI team consists of HIW's review manager, one or two peer reviewers and a lay reviewer, though HIW acknowledged that several inspections in 2014 were accompanied for training purposes by more staff. Due to the broader scope, independent hospital inspections comprise, besides the inspector manager, a clinician, an engineer and recently also a lay reviewer. In the Cancer-peer-review programme¹³, a multidisciplinary team of clinicians, a lay reviewer and sometimes an HIW inspector reviews the self-assessments and conducts the announced visits.

With its temporary assignments of peer reviewers, HIW continues the Healthcare Commission's practice to buy in external clinical expertise and invite service users rather than exclusively relying on its own staff.

The following sections summarise the findings concerning the different team members: review managers, peer reviewers and lay reviewers.

¹² full time equivalents (European Partnership for Supervisory Organisations in Health Services and Social Care, n.d.).

¹³ This programme was supported by HIW but run independently.

In 2014, HIW assigned one senior review manager for every LHB. HIW's review managers are supposed to lead inspection teams and manage the inputs from peer and lay reviewers (Healthcare Inspectorate Wales, 2015r). According to an HIW manager, only four out of the 11 review managers in post in August 2015 had a nursing clinical background, amongst them was HIW's inspection manager for the independent sector. Opinions amongst HIW managers varied on whether review managers required clinical expertise. While one HIW interviewee regarded the lack of clinical experience amongst review managers as potentially undermining HIW's credibility, another HIW participant disagreed, pointing to the clinical expertise of peer reviewers within the inspection team.

'It is likely that this dichotomy of opinion comes from the fact that HIW sits within the civil service and as a result has previously employed generalist civil servants to undertake this work. [...] The issue here is that it remains unclear whether HIW regards regulation and inspection as a professional task that should be undertaken by people with relevant knowledge and experience.' (IN14)

The interviewed peer reviewers drew a fairly positive picture of current and previous HIW review managers, praising some as 'absolutely fantastic', 'amazing and brilliant', 'very good' and 'senior individuals, who were absolutely on the ball'. Yet, one peer reviewer also mentioned problems in the past that arose from an overstrained and inexperienced inspector, who replaced a senior colleague. Peer reviewers emphasised the importance of leadership and communication skills, which includes encouraging and listening to peer reviewers, expressing appreciation and taking informed decisions. In the presence of a strong peer reviewer, some review managers were reportedly reluctant to lead the team. HIW subsequent recruitment of experienced inspectors with a nursing or social services background has made, according to an HIW manager, 'a significant contribution to the success of HIW'.

DECI reports do not contain information about the inspection team, whereas other HIW inspection reports, particularly thematic reviews and independent hospital inspections, did or do specify names (Wales Audit Office & Healthcare Inspectorate Wales, 2013) and roles (2007b, 2011) or the team composition (Healthcare Inspectorate Wales, 2012a, 2016b). The inspection manager for the independent sector can reportedly choose the external reviewers, which ensures that the team possesses the relevant competencies. It is not entirely clear whether all HIW review managers enjoy the same freedom or have the necessary experience to make such informed decisions. One HIW participant asserted that setting up the right team with experts to cover as many aspects of a certain system as possible is crucial for regulatory effectiveness. The same participant explained that new team members need to be supported in developing skills.

'They [unexperienced inspection team members] have to have that confidence in you that you are not going to laugh about their inexperience... and the fact that they've got stripped from their skill base, that's confidential and should be nurtured. Nurturing is very important in all aspects of any inspection for all parties involved in it.'
(IN13)

According to the participant, a review manager should behave in a firm and polite manner, especially when conveying negative findings and enforcement decisions. A tough inspector with 'a heavy hand' can evoke non-cooperative behaviour by healthcare managers, who thence ignore or challenge the findings. While the participant expressed her respect for the managers of inspected hospitals, she also warned that an inspector had to be vigilant, because trust can be abused. Similarly, another senior HIW manager advocated for both cooperation with healthcare providers and vigilance.

'It's a fine line between being captured, being cruised and being collaborative'. (IN6).

HIW emphasised and peer reviewers confirmed that HIW peer reviewers are selected through a formal recruitment process. No peer reviewer reported about an inexperienced fellow reviewer. However, one peer reviewer noticed during an inspection that some of HIW's earlier cleanliness spot-checks did not include a specialist peer reviewer and therefore, as she deduced, resulted in an unjustifiable clean bill. The same peer reviewer instanced an example where she had supported a small, independent hospital in reviewing its infection control policies after an inspection.

HIW very positively referred to peer reviewers as its 'ambassadors' in the health sector. HIW participants elucidated the importance of peer reviewers by acknowledging the specific expertise necessary 'to drill down' in a particular specialty area.

HIW confirmed that most of its registered peer reviewers are nurses with relevant experience. In the past, most peer reviewers were seconded by the NHS and not paid by HIW. HIW's decision in 2014 to pay peer reviewers increased their commitment, as one HIW participant stated. Peer reviewers elucidated the difficulties in the past, which resulted from the secondment. They appreciated the change in HIW's policy, i.e. to pay for their services, though two mentioned delays in the payment transfer. Peer reviewers explained that the need to coordinate the assignments with their main place of work in the NHS restricted their availability for HIW inspections, particularly when called at short notice.

Lay reviewers, i.e. service users or other members of the public, are considered an important element in HIW's inspection regimes and also in the Cancer-peer-review programme, which runs independently from HIW. According to one HIW participant, the

selected lay reviewers used to be matched with the profile of the inspected service. Typically, lay reviewers are charged with the task of approaching patients, relatives or visitors for feedback on their experience (Healthcare Inspectorate Wales, 2017c). HIW's policy to financially compensate its lay reviewers changed in 2016 and became the subject of a political debate (BBC, 2015). HIW explained the decision with financial constraints and the intention align its policy with similar bodies in the UK and Wales.

HIW organises induction and training for its peer and lay reviewers. The meetings and feedback create the opportunity for discussion and changes to the inspection methods and tools. The recruitment of new reviewers can bring in new ideas and viewpoints, which one HIW participant regarded as very positive. The interviewed peer reviewers appreciated the gatherings, that HIW had organised in 2014, yet they pleaded for more regular meetings. One peer reviewer recommended organising regular meetings, e.g. every three to six months, to exchange information between HIW and its peer reviewers, particularly to gather feedback and proposals for the improvement of inspection tools and methods.

Participants in the Cancer-peer-review¹⁴ training especially remembered the role play, which some described as a good and fascinating exercise.

'We did role play. So, what's it like being inspected or peer reviewed, and what's it like to be the reviewer. And it was a fascinating exercise. We used real data, and we were a real team. [...] I left there feeling really assured about that process.' (IN36)

The training and team-building that the Trusted-to-care spot-check reviewers described, reportedly helped them later to act as a team and discuss the findings.

4.4 Post-inspection

The findings presented below refer to the aspects and activities within the inspection process, which take place after the hospital has been inspected. This relates to the (i) immediate feedback, (ii) inspection reports and their publication, (iii) action plans, (iv) follow-up and (v) enforcement. These components are supposed to inform the relevant stakeholders about the degree of compliance with regulations and standards and, if necessary, enforce that corrective actions are taken.

4.4.1 Immediate feedback

HIW's hospital inspections usually conclude with a debriefing on site, during which the inspection team presents the findings and highlights the necessity for immediate actions.

¹⁴ Until 2016, HIW supported this programme through guidance, (lay) reviewers and organisational arrangements.

In a preparatory internal meeting, the inspection team collates, summarises and discusses their findings in order to verify and agree upon the statements to be made during the debriefing.

HIW considers oral feedback, particularly concerning actions that the hospitals will be required to do, as an effective element in the inspection regime. Particularly, independent hospital managers were said to often proactively approach HIW inspectors for specific advice during and outside inspections.

'We do have a lot of response. Because for them [acute independent hospitals] it's their life line of business. Feedback is essential to them. As a corporation and in terms of their image.' (IN13)

Peer reviewers noticed variations in the composition of participants at the debriefings, which they interpreted in many ways. Two peer reviewers saw in the mix of participants a barometer of how seriously the inspected organisation took the inspection. Another peer reviewer deduced from the attendance of very senior LHB managers a large interest in the initial cleanliness spot-checks and interpreted the later prevalence of junior managers as a sign that the inspections lost their impetus. Conversely another peer reviewer noticed that after the prominent failings in UK healthcare LHBs increasingly valued HIW inspections.

HIW intends to apply a non-confrontational approach and present both, positive and negative findings.

'I will always give a rationale as to why I have formed an opinion or a judgement. [...] And you can't rely upon a list. Not with the big players. They sense weakness. There is no other word for it. [...] "When you've done an inspection, and you're sitting in a board room or conference room or wherever it may be, and you have two or five reviewers, and you have six people, seven people at the other side of the table, all ready to challenge every review, every remark unless you can evidence it, you have to be extremely sure of your facts, and you have to know how to move things along".' (IN13)

According to the peer reviewers, HIW's inspection teams carefully check and triangulate evidence prior to the debriefing.

'If only one person saw something, you had to triangulate. [...] You couldn't report at the end of the day something that only one person saw, unless it was really serious.' (IN44)

Reviewers sometimes reported about challenging and emotional discussions, particularly with healthcare managers who took criticism personally.

Prior to 2015, NHS managers, other than the ward manager, were usually not interviewed in the inspection and thus the debriefing constituted the first opportunity for

senior managers to enter a dialogue with the reviewers. Especially, the presence of the (clinical) peer reviewers gives their counterparts at the hospitals the possibility to learn at first-hand about the findings and challenge them.

‘A strength is that we use peer reviewers, that we immediately feedback our findings at the end of the inspection. So, if the... ward, or director nurse or whoever is there want[s] to challenge, then we have that challenge then, and we come away knowing exactly what we are going to say about them, and that there is no surprise.’ (IN18)

It is HIW’s policy to address quality and safety issues that require immediate corrective actions at the debriefing and by a management letter to the healthcare organisations within two days after the inspection, copied to the Welsh government for follow-up. Examples of immediate resolution can be found in HIW’s (2014g, 2015j) DECI reports. According to its own account, HIW issued 68% of immediate assurance letters within the target time in 2014/15 (2015c). An HIW interviewee described a rigorous handling of serious breaches in independent hospitals, though a rare phenomenon. It is unclear whether all HIW review managers demonstrate a similar behaviour and commitment in NHS inspections, where the requirement for immediate actions is not unusual.

4.4.2 Reporting

As HIW (2015s) depicted in its strategy map, the inspectorate considers reporting as a means to provide assurance and promote improvement. Factors that help to increase regulatory effectiveness through reporting are (i) addressing and activating the target readership, (ii) accuracy and timeliness, (iii) accessibility and (iv) readability.

Opinions amongst HIW participants varied concerning the target readership of inspection reports. Given the length and ‘impenetrable’ language of HIW’s previous reports, one recently recruited HIW manager presumed the healthcare professionals as the target audience in the past. Another HIW participant considered the patients as the current and ultimate focus, because their informed choices increase the effectiveness of an inspection regime.

Although, as one HIW manager explained, in theory people opt for healthcare providers with positive inspection results and thus force poor healthcare providers to improve or terminate their services, in reality, other factors come into play such as geographical distance and cost. Allegedly, HIW has experienced many requests for information and inspections reports concerning independent hospitals. Based on her conversations with potential and actual users of independent hospitals, one HIW manager considered the majority of users as well-informed, using various sources of information to choose amongst independent hospitals. According to the same participant, cross-reading

inspection reports has been a common practice within the small and competitive independent hospital community.

While HIW admitted that NHS patients, unlike private patients, typically do not have a free choice amongst different hospitals in Wales, the inspectorate emphasised the right of the public to learn about hospital inspection results. As an HIW participant explained, negative reports may prompt the population to approach their local representatives. Moreover, local or national media have been instrumental in raising awareness and political pressure on healthcare providers through interventions of social and political actors. Another HIW interviewee referred to the role of the Welsh government.

'Ministers did, both individually and collectively, so, individual reports and individual organisations, they were taken very seriously and acted upon.' (IN6)

For consistency reasons, it is the task of HIW's reviewer manager to draft the inspection report and that of the respective peer reviewers to review the draft. The interviewed peer reviewers appreciated the opportunity to revise incorrect or wrongly contextualised formulations in the draft reports. Some peer reviewers complained that, in former inspection regimes, they were at times excluded from reporting. The exclusion led to inaccuracies in the published reports, particularly when the author, i.e. the HIW review manager, had no clinical background.

Within three weeks after the inspection, HIW (2014f) aims to send the draft report to the inspected body for a factual accuracy check and within 3 months to publish the final report. Target times were previously longer, i.e. twelve weeks for draft reports and four months for the publication. During 2012-2013, HIW massively exceeded its targets with some inspection reports being published 12 months and more after the inspection (Cairns, 2013; Duerden & Hopkins, 2013; Taber, 2013). Timeliness improved during 2014/15 with HIW issuing 61% of the draft and 67% of the final inspection reports within the target time (2015c). However, 17% of the inspection reports were published after more than 100 days, four of which after more than 150 days (Healthcare Inspectorate Wales, 2015c). HIW's managers were aware of the reputational damage that the severe delays, which were also raised during public inquiry in 2013 (Health and Social Care Committee, 2014), caused.

HIW participants mentioned a variety of factors, which caused or contributed to the severe delays in the past. Firstly, there were capacity problems resulting from turnover of staff between 2012 and 2014, maternity leave and long-term illness. Secondly, delays were explained with a perceived lack of leadership resulting from the announced change of HIW's senior management in 2012/13 and thirdly, HIW's obligation to produce bi-

lingual reports consumes extra-time. One peer reviewer explained that due to their secondment in the past, peer reviewers lacked the time and financial incentive to write their part of the report immediately after the inspection.

HIW publishes reports on its website. Its user-unfriendliness and the lack of updates were criticised during the public inquiry (Health and Social Care Committee, 2014). Plans to overhaul HIW's website existed in 2012 but were not implemented until 2014. Most LHBs present inspection reports and improvement plans either on their website or via links to HIW's website (Abertawe Abertawe Bro Morgannwg University Health Board 2014; Betsi Cadwaladr University Health Board 2016). LHBs also report about inspection results in their annual reports. The DECI in 2014/15 generated a large quantity of inspection reports, which informed HIW's (2015n) thematic report across Wales. Moreover, HIW published for each LHB in August 2015 annual reports that highlight key themes that were identified during HIW's inspections. The inspection manager for the independent sector reportedly encouraged hospital managers to share good practice in order to learn from each other and improve healthcare.

HIW uses public and social media to announce inspections and inspection results. HIW admitted the challenge to convey a balanced message to the public through the media, given the media's preference for negative news.

'Health is a big and constant story and good news stories don't make the media, means that, I think the public receives a very misleading picture of the state of healthcare in Wales through the media. And it's very challenging for us to give them a more balanced presentation'
(IN11).

Many HIW managers saw the need to improve not only timeliness, but also the content, structure, language and style of reporting. Since 2014 HIW has introduced changes to make the reports more consistent and readable for all potential readers, which considering conflicting expectations poses a dilemma. One HIW manager, informed by her regular contact with patients, stated that 90 percent of patients of independent hospitals would not appreciate the new reporting format. Another HIW interviewee wondered whether the public finds word-of-mouth recommendations more meaningful for their decision-making than inspection reports.

The most obvious changes in the DECI reports since 2013/14 relate to structure and layout. HIW managers emphasised that the new reporting format contained explicit conclusions about the provided healthcare and the judgement about the healthcare service, which the previous reports lacked. In its attempts to make a judgemental statement, HIW has neither returned to its former traffic-lights scheme nor to CQC's recently introduced framework.

'Because if you look at the work that CQC have put in, to say whether it's outstanding or whatever, we simply don't have the capacity to introduce that level of consistency at the moment.' (IN11)

4.4.3 Action plan

HIW expects the inspected organisation to submit a draft improvement plan in response to negative findings. Former and current HIW managers described their experience with improvement plans¹⁵ as variable.

'If you look at some of the action plans that we reviewed recently, [name] and I, there were some that were very good, and there were others where there were lots of words, and lovely language, but actually it was a meaningless pile of management nonsense.' (IN14)

One peer reviewer therefore proposed that HIW should consult the respective peer reviewers concerning the quality of improvement plans.

DECI reports include either the agreed improvement plan or a template as an appendix. Every DECI report states that the improvement plan, which the inspected organisation is required to submit 'within two weeks of the report being published' (Healthcare Inspectorate Wales, 2015f), will be published on HIW's website. Many improvements plans have not been published in spite of being submitted and agreed (Healthcare Inspectorate Wales, 2014b) and reminders by LHBs (Cardiff and Vale University Health Board, 2014). This shows, as HIW admitted in 2015, that the process was not working. At the time of publication, the action plan might have already been partially implemented.

'We write our report, we publish it within three months, we receive an action plan back from the health board which is also published on our website. And, by which state, when we are publishing our report, actually, the health board has put a lot of this action into place.'
(IN22)

4.4.4 Follow-up

With NHS organisations responsible for the implementation of corrective actions and accountable to the Welsh government, HIW's role used to end at assuring the quality of the submitted action plans. This architecture initially worked, but then 'decayed' with very little follow-up and further assurance sought by the government.

'the theory was working OK: the inspectorate inspects, it quality-assures the action plan, basically says: Yes, the action plan, if they do it, will actually meet all these things, but because we are not legally able to hold you to account, because we don't have that kind of relationship, we'll give it to you, health department. [] It worked for five years. [] but then that kind of decayed - that is the best word to

¹⁵ In its earlier reports, HIW uses the term 'action plan', since 2014 'improvement plan'

say - after 2009, because of the reorganisation, we ended up with.'(IN6)

With regard to the importance of external follow-up visits and accountability mechanisms, several HIW managers and reviewers regarded the rare or inconsistent follow-ups a weakness of HIW's inspection regimes. However, one participant claimed that HIW conducts follow-up visits when necessary and expressed her view that the healthcare organisations implement the improvement plans in anticipation of a possible follow-up visit.

In its efforts to maximise the impact of its inspections, HIW (2015c) has reviewed its follow-up practice. Since 2014/15, its inspection reports have documented follow-up of previous inspection findings (Healthcare Inspectorate Wales, 2016b, 2016e), including those of the Trusted-to-care spot-checks (Healthcare Inspectorate Wales, 2015m, 2015u). Moreover, HIW conducted six follow-up visits in 2014/2015. Four of those visits were, however, prompted by the legacy of HIW's internal problems in 2013. All six follow-up inspections were announced, which in the opinion of one HIW interviewee, had no influence on the findings.

For practical reasons, HIW's follow-up visits at NHS hospitals are not necessarily conducted by the same team that carried out the preceding inspection. While one peer reviewer considered the same team composition as ideal, conversely, HIW relies on the consistency of its inspection methodology and the review manager. In the independent sector, HIW conducts as many follow-up visits 'as necessary'.

'Depends on the criteria, I am just trying to think ... As many [follow-up visits] as necessary, but we will still monitor their plan, and compliance, that is normally by email to confirm. In terms of their action plan, they may submit once, every twenty-four hours for the first seven days, depending on how serious the breach is. Then it goes to weekly to tell us the progression by which time they may have had another one or two visits anyway.' (IN13)

4.4.5 Enforcement

On its own, HIW has no regulatory powers to put an NHS organisation under special measures, fine or close it down, in contrast to CQC in England. Conversely, HIW uses several formal and informal mechanisms to influence compliance and improvement. Thereby, the inspectors should use their own judgement and not lose sight of the main goal of regulatory inspections, as a senior manager explained.

'Compliance doesn't give you assurance, it gives you compliant behaviour. [...] A safe hospital is much more than be[ing] compliant

with regulations. It is actually demonstrating behaviours of safety, a culture, a climate, an active management of risks.’ (IN6)

According to this participant, HIW interacts with the inspected hospital through negotiation. This includes tactical manoeuvres like threatening the hospital to take enforcement actions such as closing a facility, to require weekly meetings and progress updates, or to publish weekly updates and statements. Although this participant stated that ‘there was nothing stopping HIW closing a unit down’, to date this has not happened.

‘There’s a little bit in those formal systems, so you got to have a little bit of flexibility, because if the law doesn’t say it, interpret the law ... to give it a leverage.’ (IN6)

The participant instanced severe, but admittedly very rare cases, where HIW tested ‘the limits of legislation.’ She did not see the need for extra powers.

‘The publicity, the publication of information about the organisation would be enough leavers. To have the ability to fine you won’t do anything [...] action plan, updates, and letters.’ (IN6)

Due to the Welsh government’s responsibility to manage NHS performance, HIW forwards relevant information to the Welsh government. One HIW participant instanced the example of a serious issue that HIW reported by letter to the government in 2014. As a result, the Welsh government contacted the LHB for further explanation on the corrective actions to be taken.

In the past, HIW had exercised influence through informal contacts to the government. This included as a former HIW manager stated ‘occasionally a phone call to the minister’, which another HIW manager considered unthinkable for the CQC to do. Until April 2014, information between HIW and the Welsh government was exchanged, and action taken on an ad hoc basis. Since then, formal mechanisms are in place to deal with serious issues. Besides the regular bi-annual meetings, HIW can ask for an extraordinary meeting to open a case and advise the government together with the Wales Audit Office to escalate and enforce measures for a particular NHS organisation (NHS Wales, 2014). The framework comprises four escalation levels.

Several HIW interviewees regarded the close interaction between HIW and the Welsh government as very effective. One participant weighed the potential benefit of receiving more enforcement powers with the legal challenges and the need to train reviewers in how evidence findings appropriately. Although considering the CQC regulatory role as more powerful than HIW’s, another participant admitted that the CQC refrains from closing NHS premises.

Several HIW interviewees deemed the existing powers over the independent sector sufficient, which include imposing conditions or sanctions. Although HIW has the authority to revoke the registration of an acute independent hospital, this never happened. Nevertheless, one HIW manager associated HIW's regulation powers as decisive for the higher effectiveness of HIW's independent hospital inspections compared to NHS inspections. Independent hospitals in Wales are, however, much smaller in size and scope of services than their giant NHS counterparts which are subjected to closer scrutiny, exercised by numerous review bodies and schemes.

'The bigger question is the extent to which such a fragmented approach to regulation and performance management is the most effective way to drive improvement of NHS healthcare in Wales.'
(IN14)

4.5 Wider impact

Neither the findings from the document review nor the interviews suggest that HIW had installed until 2015 mechanisms to regularly and systematically assess the effectiveness of its hospital inspection regimes¹⁶. This makes it difficult, if not impossible, for HIW to assess the impact of its inspection regimes. Some sporadic follow-up visits had been conducted in the past which assessed the progress hospitals had made in implementing the action plans. The documented follow-up of previous inspection findings during subsequent inspections since 2014/15 could be a first step to establish internal monitoring and evaluation mechanisms (Healthcare Inspectorate Wales, 2016b).

Judging from HIW's reported sporadic follow-up, evidence provided during the Welsh Assembly's inquiry and the research interviews, it seems that HIW has been effective in some areas and with some healthcare organisations. An example are the follow-up visits, which HIW conducted as part of its cleanliness spot-checks and which found that 'a number of the issues we identified had been addressed and that staff had worked hard in order to achieve this' (Healthcare Inspectorate Wales, 2012b, p. 27).

Another example are the announced follow-up inspections in 2014/15, which showed varying degrees of progress amongst the NHS wards (viz. section 4.4.4 Follow-up). The reports declared 'excellent progress' only for one of the four wards revisited in 2014 (Jones, 2014) and required one of the two wards revisited in 2015 to complete a further improvement plan (Healthcare Inspectorate Wales, 2015e). HIW's (2015c) annual report presents the follow-up visit in March 2015 as evidence of HIW's impact, without mentioning that it was announced. Several unannounced DECI reports, which made

¹⁶ In 2016, HIW (2016d) did, however, evaluate its homicide investigations.

reference to previous inspection findings, expressed disappointment about several previous findings that had not improved (Healthcare Inspectorate Wales, 2015m).

In general, HIW participants seemed in agreement that the inspection results were more positive in the independent sector and inspections comparatively less effective in the NHS.

'In fact, it's one of those things we are coming across this year, certainly where they are saying: You know, you can regulate very stringently, which you do, which in most parts they welcome because it embeds good practice, good attitude, good culture working. What about the NHS? You read their reports and it's repetitive, repetitive, repetitive, year after year.' (IN13)

4.6 Conclusion

The findings showed several, mostly externally-driven developments, which positively or negatively affected HIW's inspection regimes and thus regulatory effectiveness, such as:

- (i) The prominent failings in UK healthcare raised awareness for regulatory effectiveness amongst policy makers, healthcare professionals and HIW itself.
- (ii) The self-assessments, which the government introduced to shift the responsibility for quality assurance to healthcare providers, overburdened HIW and thus undermined HIW's regulatory effectiveness.
- (iii) The cooperation with other review bodies has been instrumental in sharing data and soft intelligence and strengthened HIW's clout.
- (iv) The staff vacancies and turnover in 2012-14 weakened HIW's capacity to conduct, report and follow-up inspections. With the new recruitments in place, HIW managed to strengthen its analytic capability and inspection capacity.

HIW has faced several difficulties in implementing its inspection regimes. The limited funds and capacity have often forced HIW to strike a balance between different types of activities and tactics. HIW is not able to annually inspect every NHS hospital and therefore has to pre-select inspection sites. The lack of ward-specific data does not wholly support targeted inspections, despite HIW's repeated claims to apply a proportionate or risk-based approach. Given the variability of performance across wards, it seemed wise for HIW not to entirely rely on retrospective, self-reported, aggregated data, but in addition to use soft intelligence and inspect hospitals with good performance data. The small number of inspections conducted in 2012-14, delayed reports and insufficient follow-up in the past jeopardised the effectiveness of HIW's inspection regime. HIW did not sufficiently show local presence, which would have kept hospital

managers on their toes, and thereby presumably failed to detect non-compliance at the uninspected hospitals.

External reviewers with inside, clinical expertise (peer reviewers) and personal experience and empathy (lay reviewers) are recognised as a major strength in HIW's inspection regime. HIW has been honest in admitting that the scope, depth and duration of its inspections do not facilitate a general statement about the healthcare quality of an inspected hospital. Room for improvement was identified in the post-inspection process, especially concerning the delayed reporting and infrequent follow-up. HIW has recognised its (previous) shortcomings and taken steps to solve issues.

Over the years, HIW's inspection regimes underwent significant changes regarding thematic scope, frequency and methodologies. Inspection regimes adapted to external events, new policies and findings to maintain or increase their effectiveness. Differences exist in the regulation and inspection between NHS and independent hospitals, the legitimacy of which is difficult to comprehend. Differences are also noticeable in the inspection results. The findings suggest that HIW inspections have been more successful and thus effective in independent hospitals, which seems to result from a variety of factors. These, amongst other findings, will be further studied in the next chapter, which examines HIW's inspection regime from the healthcare managers' perspective.

5 Being inspected

This chapter describes HIW's hospital inspections from the perspective of inspected healthcare organisations. It summarises the interviews with 31 NHS and eight independent healthcare managers and includes statements by peer reviewers when made from a 'being inspected' perspective. The first section sets the scene for the analysis of the three process stages. The latter sections describe how the different components of the inspections were conducted and the problems that occurred. Moreover, the chapter examines which elements worked or did not and summarises the changes that the managers of the inspected organisations recommended to increase regulatory effectiveness.

5.1 Situational context and background

Although some interviewed healthcare managers alluded to a possible political motivation behind certain actions or omissions by HIW, none of the participants seriously questioned HIW's professional objectivity. Participants from the independent sector, which HIW has been regulating since 2006, acknowledged HIW's impartiality which they contrasted to the Welsh government's disinclination towards the private sector.

NHS managers stated that the reorganisation of NHS Wales in 2009 had led to larger size and increased complexity in some Local Health Boards (LHBs). This widened the divide between the executive managers at the top and the healthcare providers at the frontline and thus made quality assurance more difficult. HIW was perceived to play a potentially beneficial role by informing and externally validating the LHB's internal assurance systems.

As in the previous chapter, the 'small country' context of Wales was seen as both, positive (facilitating conversation and shared experience) and negative (self-centred, with a limited pool of reviewers and the risk of closed ranks or capture). Moreover, healthcare managers noted that the reductions in public expenditures had increased the pressure on NHS hospitals to an extent that made it difficult to provide effective, safe and compassionate healthcare. NHS managers saw a role for HIW in addressing factors, that compromise healthcare, in its reports and communication with the Welsh government.

None of the participants questioned the necessity of external inspections, by contrast many hospital managers advocated a strong inspectorate with competent reviewers and robust inspections. Participants generally considered HIW's focal topics relevant, some few topics were, however, classed as 'whims'. Several NHS managers, including peer reviewers, considered the DECI's focus on nursing care as rather narrow, proposing a

broader thematic spectrum and multidisciplinary approach. During 2014 and 2015, many participants noticed modifications in the design, themes and particular topics that HIW inspections pursued, such as meal times, infection control and medicine management.

Independent hospital managers noted a more thematic focus in 2014, contrary to the development in HIW's NHS inspections, where the thematic scope had noticeably widened. Opinions amongst NHS managers on what would constitute the best focus for HIW's inspections varied. Suggestions ranged from reviewing hospital governance systems at the top level to healthcare delivery at ward-level as well as patient pathways across different healthcare services. Some participants suggested an improvement-oriented inspection approach, using thematic clusters, which, when the hospitals met or exceeded the expectations, would move on to the next cluster.

Most of research participants appreciated the Cancer-peer-review programme, which runs independently from HIW, as a useful and good model to transfer professional knowledge and best clinical practice.

'It's an opportunity to think about your own service and to comment upon it. Sometimes, none of us are perfect, and we can learn from each other with peer review, which is why I would encourage anyone to be a peer reviewer, to go and have a look at somewhere else.'
(IN15)

Some healthcare managers critically noted that the Cancer reviews did not coordinate with HIW's hospital inspections.

5.2 Pre-inspection

The findings presented under the pre-inspection process refer to those aspects or activities within HIW's inspection regimes, which take place before the inspection team arrives at the hospital. These components are supposed to direct the healthcare organisations, establish a common understanding of the expected performance and inform HIW's decisions on inspection topics and criteria as well as inspection sites.

5.1.1 Healthcare standards

NHS managers reported that frontline staff were familiar with the 'Fundamentals of Care'. Yet, the acceptance of these professional standards amongst NHS staff did not automatically lead to positive inspection results. Due to the resource limitations and work pressure, NHS participants found it challenging to consistently adhere to these standards. According to one NHS participant, the healthcare standards 'tend to drive mediocrity' in large NHS organisations rather than quality improvement.

'In an organisation as large and complex as any NHS body, it would be difficult ever to other than be somewhere in the middle, because you will get variance and inconsistency across services. (IN10)

Similarly, another participant advocated for more ambiguous standards.

'Patients deserve excellent care, really. And if you set your standards low and everyone can tick the box, ... then there is no great impetus to improve.' (IN3)

Other participants referred to particular sets of standards and guidelines, which they considered more demanding and thus potentially more effective to drive improvement. Numerous NHS managers criticised the room for interpretation that the generic standards left and illustrated diverging interpretations of certain standards during inspections.

'If the inspectors are not grounded, they may think of a platinum standard, that we would struggle to meet even in a good day or a medium day.' (IN46)

Many healthcare managers advocated for more specific, quantifiable outcome-oriented indicators, which would give less cause for diverging interpretations. None of the independent managers conveyed difficulties or disagreements with HIW's interpretations of the standards. Only one independent manager referred to occasional inflexibility of some peer reviewers.

'There is sometimes interpretation by some of the inspectors that are bit over-dogmatic, I would say that [name of inspector] as the lead inspector has a reasonable sense of balance about what's reasonable.' (IN7)

In general, independent healthcare managers expressed more positive views concerning the standards than their NHS colleagues. The appreciation for the standards did not seem to derive from the regulatory status, as some HIW interviewees had suggested (viz 4.2.1 Healthcare standards). Essential for the acceptance and thus effectiveness of the standards was, as one participant explained, the involvement of the independent sector in the development process.

'My view is that the current regulations and the current standards are reasonable, because we understand what they are trying to achieve.' (IN7)

In the interviews in 2014, several NHS participants asserted the need to revise the healthcare standards and thereby welcomed the invitation for healthcare organisations to participate in the review process. After the review, one NHS participant argued that the revised standards had not sufficiently incorporated the participants' contributions in 2014/15 and thus failed to foster ownership.

5.1.2 Registration

Until 2015, only one acute independent hospital was newly built and registered. The participants reported that HIW's guidance in the preparation process was constructive. The early involvement of and close cooperation with HIW resulted in the successful registration of the new premises. The interviewed hospital managers confirmed that the regular meetings and contact persons on each side helped to establish a professional relationship and mutual respect.

'They [HIW]... really really worked incredibly well with us. So, we went to regular meetings with them. We would give them updates on the plans. We would talk through everything [...] And that would give us a really good involvement and articulation with them about what we were doing. Were we going to meet the regulation and compliance - to see if we were still on track and to ensure that we were going to get commissioned and approved ... on time. [...] If ever I rang HIW they would always come back to me.' (IN1).

While the hospital managers appreciated HIW's efforts before and during the registration, they expressed, however, their disappointment about the infrequent inspection visits thereafter.

5.1.3 Self-assessment

Participants generally regarded self-assessments as a useful means to strengthen responsibility and described the initial self-assessments as rigorous. Nevertheless, many interviewees highlighted the difficulties NHS organisations faced due to their restructuring in 2009 and insufficient guidance from HIW. From the lack of recent detailed feedback, the participants concluded that HIW no longer had a role in reviewing the self-assessments.

'It was a huge undertaking by Healthcare Inspectorate Wales. I think they underestimated the volume of information they would receive. Because, health boards, that were probably trusts at the time, were very unclear of exactly what was required. And of course we didn't want to do our organisations an injustice. So, the first two years, I think it was very difficult on both sides. Over time, they've withdrawn from that process. So, they don't actually come in now, and assess us against the standards, and they rely on a self-assessment process by the organisation itself.' (IN29).

As several NHS managers stated, HIW's perceived withdrawal and lack of feedback had undermined the motivation within LHBs to conduct thorough self-assessments. Several participants highlighted the continuing need to embed the healthcare standards and the self-assessment process vertically across their organisations. Moreover, participants reported about deviating self-assessment mechanisms, tools and attitudes, which

caused variability in format, quality and content of annual governance statements and thus obstructed comparison and benchmarking across the LHBs. The assumption that HIW's inputs could be reduced, once self-assessments had been established, appeared to be unrealistic. This became evident during the interviews with NHS participants, who considered their organisation as not sufficiently mature to be left alone with the self-assessment.

'They rely quite a lot on self-assessment, and self-assessment needs to be done very carefully, because otherwise it will be like 'turkeys voting for Christmas'.' (IN17)

Regarding the onerous paperwork and the insufficient validation, many interviewed NHS managers assessed their efforts to complete the self-assessment as not proportionate. Their negative experience and HIW's apparent resource constraints made several participants question HIW's ability to provide accurate assurance and more generally the effectiveness of the entire approach.

Independent hospital managers recalled HIW's efforts to introduce self-assessments in the independent sector in 2008/9 (Jewell & Wilkinson, 2008), but explained that those were abandoned after HIW's convoluted electronic assessment tool proved to be unsuitable. Participants, however, explained that the independent hospitals share the documentation of their internal assessments with HIW reviewers.

5.1.4 Selection of inspection sites and pre-inspection information

Most NHS managers said they did not know how the HIW had selected the inspected sites. Some interviewees did not see a rationale in HIW's choice of inspection sites, arguing that a particular hospital or ward had been frequently inspected without any evident reason, while other wards remained uninspected for years. One participant interpreted the absence of HIW inspections at her hospital as a good sign:

'They [HIW] will be looking at public figures around C[lostridium] Diff[icile], or MRSA, and they'll go in and target. So; they are... They are looking at where there are issues and then going in and reviewing, in my experience. We haven't had a visit from them.'
(IN31)

In the light of HIW's rare inspections in 2012-14, this interpretation seems rather speculative and bearing the risk of false assurance.

Other participants presumed or knew that HIW used prior intelligence such as complaints from the ombudsman, poor performance data or information from Community Health Council inspections to preselect particular NHS hospitals and wards. One NHS interviewee referred to the past, when despite increasing rates of *clostridium difficile*, HIW did not undertake an inspection. More fundamentally, one NHS manager

questioned whether HIW's inspection regime should target weak services, arguing instead for a representative or random selection of inspection sites.

Many NHS participants commented on the variability of care within the same hospital. Participants shared the common view that healthcare managers should not be involved in the selection of the inspection site, due to the temptation to pick the best-performing wards. Therefore, they regarded the independent selection of inspection sites by HIW as an important factor for rigour and potential effectiveness.

Some interviewees noted that HIW's initial choice of the inspection site was not irrevocable and expressed their appreciation for HIW's flexibility not to inspect a ward, which had only a few patients or faced a problem with nosocomial infections caused by *Norovirus* or *Clostridium difficile*.

Some participants doubted that HIW made sufficient use of available data. Peer reviewers and participants with specialist knowledge recommended analysing certain hospital performance data and databases.

'[...] the Welsh Healthcare Associated Infection Programme - they gather data on a whole range of markers and publish it, and health boards are required to make that data publicly available on their websites. So, that is actually a good model that isn't in place in England at the moment.' (IN3)

Interviewees also advocated for an intelligent use of data, arguing that transparent organisations tend to report more robustly than non-transparent organisations with a poor safety culture. One peer reviewer conceded that HIW would find it difficult to get access to decisive, ward-specific data such as hand hygiene, infection control, pressure ulcer and attrition. Another peer reviewer highlighted the potential inaccuracies in the self-reported data.

'Up to a couple of years ago, almost without fail we have got ward sisters who do monthly hand hygiene audits, hundred percent, hundred percent, hundred percent. [...] I have no faith in self-assessment, in any way, shape or form.' (IN43)

Similarly, participants, referring to the prominent failings in UK healthcare, warned that review bodies should not rely on self-reported information without validating site-visits.

'You need to validate. If we are saying that everything is wonderful, which we are not, but if we were, you need to go in and validate anyway, don't you? So, I think their programmed visits need to sharpen up and so that it's consistent.' (IN31)

5.3 On-site inspection

The findings presented below refer to the aspects and components which are relevant at the time when the hospital is inspected. This relates to the (i) frequency, duration and depth, (ii) mode, (iii) inspection methods and tools as well as the (iv) inspection team. These factors are instrumental in detecting whether a hospital is compliant or not with the respective regulations and standards.

5.3.1 Frequency, duration and depth

The participants from the independent sector expected annual HIW inspections as an integral part of their quality assurance systems and as a service in exchange for the fees, which were introduced in 2011 (Healthcare Inspectorate Wales, 2013a). One independent manager contrasted the rare HIW inspections with the regular CQC inspections.

'[Name of organisation] are used to the Care Quality Commission where they came out religiously every year and inspect. And then you had Healthcare Inspectorate... that we never saw a sight of for two years, no contacts or anything.' (IN1)

Although none of the independent managers recognised a negative effect on healthcare provision, resulting from the reduced frequency, one participant acknowledged that such a discontinuity could induce non-compliance. Also, several LHB managers called for a higher frequency of HIW inspections, such as six-monthly inspections per hospital, covering different seasons.

As the interviews progressed in 2014, NHS participants were less likely to criticise the lack of inspections but started instead complaining about the burden of inspections. Apart from HIW's resumed DECI and the LHB's internal inspections, participants referred to Community Health Council and Trusted-to-care spot-checks. Against the background of external and internal inspections, senior LHB managers felt over-inspected

'I had [counting] fourteen inspection in, I think it turns out to be about eight weeks [...] we ended up having Welsh Government inspections, the DECI inspections and the Community Health Council inspections, which I haven't counted in those fourteen. But they were all running at the same time, so the staff were beginning to think "Well, who's coming next?" And some of them, were the same wards... Because we also run our own-' (IN27)

Usually, NHS participants did not specify how many external inspections they considered adequate. One NHS manager regarded three DECI at three different hospitals within three months as too frequent, explaining that the DECI could lose their power, because people desensitise. Upon further inquiry, it became clear that it was not the frequency as

such, but the recurrent negative assessment results that caused frustration and desensitisation. The interviewee explained that middle-level NHS managers do not have much control over resources and thus feel powerless. She and other participants stated that frontline staff, who often presume that their facilities are selected based on prior intelligence, become anxious, when external inspections happen in short intervals. Some participants considered longer intervals between the inspections within a LHB as potentially more effective than the close succession of DECIIs in the last six months of 2014. They argued that with longer intervals each inspection report would be read and acted upon more thoroughly. Conversely, other participants, amongst them one peer reviewer, noted a positive effect of frequent inspections, which allegedly results from frontline staff and managers, who recognise the positive role that inspections, which focus on learning and supporting, play in quality assurance.

With reference to the Trusted-to-care spot-checks, two interviewees advocated brief inspections, which combine several hospital wards. They argued that skilled reviewers would be able to quickly identify issues. The managers of independent hospitals, which are smaller than most NHS acute hospitals, considered the current one-day inspections as adequate and effective. One independent manager, however, regarded the 'inspection and support system in England' for independent hospitals as 'more robust' than HIW's. Though, she and other independent managers acknowledged that HIW inspections were thorough thanks to HIW's inspection manager and reviewers. Similar views were expressed by most NHS managers.

'They were thorough. Very thorough. I think maybe, better, more thorough this time, with a more rounded understanding than previously. I think sometimes, previously, they just picked on anything to be able to report.' (IN42)

Informed by her previous experience in England, one NHS participant considered two-day inspections with specialist reviewers as very effective. In the past, she had experienced CQC's hospital inspections as 'shallow', often missing critical issues. Several other managers saw a potential benefit deriving from unannounced out-of-hours visits, referring to those as common practice in HIW's mental healthcare inspections and the Trusted-to-care spot-checks.

'It helps you to see how the hospital works together or not at night, what challenges the staff face at night.' (IN45)

'Because staff are a lot shorter at night that they are by day, but their patients aren't cut down.' (IN41)

Many Trusted-to-care spot-checks took place during evening or early morning-hours and four during weekends. A peer reviewer admitted, however, that this intensive regime, which covered 70 wards within seven weeks, was very tiring.

5.3.2 Inspection mode

Several participants considered both inspection modes, i.e. announced and unannounced, as potentially effective, depending on the circumstances, design and purpose. Given the advantages and disadvantages of both, some healthcare managers contemplated on a mix of unannounced and announced inspections.

‘You could have a double tail model, so you could have that they come unannounced this Friday, but actually in a fortnight's time, we'll come back and sit down with you to have a discussion.’ (IN30)

The majority of NHS and independent managers expressed their preference for unannounced inspections. They argued that unannounced inspections were more authentic, because they left no time for preparation, therefore reflected the reality of healthcare (on that day) and thus provided accurate assurance to senior managers and the public. Some managers explained that their appreciation for unannounced inspections was rooted in the culture of their organisation, the confidence in the organisational settings and the presumed positive effect on organisational learning. Nevertheless, many participants also highlighted that HIW's short, unannounced hospital inspections provide only a snapshot view, which might not be representative.

‘An unannounced visit, that's sort of a very short visit, just gives you that snapshot view of what happened on that day, at that time, in those circumstances. And that can be very positive in one way, but it also can have negative effect, in the sense that, there may well have been extenuating circumstances to provide a situation on that day. Or it could give you a false sense of security. It depends on how long the visit is, and the purpose of the visit.’ (IN28)

Therefore, some interviewees warned against generalising specific findings. Conversely, some senior NHS and independent managers stated that they were keen to learn whether a healthcare service was functioning under difficult conditions or when the senior management team is not around, and thus test the organisational systems.

Participants associated unannounced inspections with potential risks for patients, arguing that unexpected inspections distract or pull away clinical professionals from administering medication or patient care. Some examples were instanced, where managers had stepped in to fulfil nursing duties on the ward. Moreover, participants noticed increased levels of stress amongst frontline staff resulting from the unexpected visit.

'It is nerve-wrecking for some nurses' (IN38)

Conversely, another interviewee instanced an announced inspection that caused distress for the staff for many days in advance.

Healthcare managers appreciated HIW's efforts to create a non-threatening atmosphere during the inspections. Though, these efforts did not necessarily erase or diminish the anxiety amongst frontline staff. One interviewee had experienced HIW inspections in NHS hospitals as more intimidating than the much friendlier inspections in the independent hospital, where she currently worked. Some healthcare managers stated offering moral support to strengthen their subordinates' confidence. A very positive attitude expressed one participant, who attempted to demystify HIW's inspections by encouraging fellow professionals to become peer reviewers. Some had gone further in their attempts to help their staff 'understand what to expect' and to reduce the anxiety.

'We have prepared them, that if they meet and greet, and are warm and welcoming, and host the inspectors, that that is a very positive first impression for the ward. So, I think there is an art to receiving the inspectors. [...] Certainly, I've done work directly with my previous hospital to say to the ward sisters "They might be looking for this, so make sure you highlight this good practice."' (IN37)

NHS organisations have also introduced internal inspection schemes and some piloted unannounced DECI-type mock-inspections, using HIW's criteria and tools.

Interestingly, one NHS manager, who initially mentioned that the frontline staff felt 'inspected to death', described that the unannounced internal inspections helped in preparing frontline staff to deal with external inspections.

Experiences and perceptions of what constitutes an unannounced or announced inspection varied amongst the participants. Firstly, participants admitted that the unannounced inspection would not be a surprise anymore on the second day.

'If we went in at six o'clock in the morning on one ward, and we were going to do another ward at twelve o'clock, those wards would know we were already there. So, the first ward is fine and it's unannounced. But the second ward is not unannounced.' (IN41)

Secondly, one participant stated that given the history of issues and inspections, the healthcare organisation, that she worked at, could expect at any moment a CQC inspection. Thirdly, another participant considered the unannounced Trusted-to-care spot-checks in 2014 as announced:

'We knew that they were coming, but we did not know when they would be coming. It was in a two-month time slot. [...] the one we just had, 'Trusted Care'. It was unannounced but announced. You

know what I mean. Didn't do it. They turned up when they turn up and we see what happens on the day. So, to be fair, we did not change anything because we did not know where they were going or when they were coming.' (IN16)

Lastly, an NHS participant had previously experienced that the LHB's Chief executive was informed by phone half an hour before the inspection team entered the selected ward. In this interim period, the nurses on the ward can be and, as the participant had witnessed, have been replaced by senior nurses. In October 2015, another NHS manager noted that this practice had stopped.

Participants acknowledged that announced inspections give the healthcare organisation the opportunity to

- ensure the availability of staff, which will be particularly valuable for governance reviews and investigations
- vacate appropriate venues for interviews and meetings
- compile sufficient copies of relevant documentary evidence, which are typically required by thematic reviews and
- prepare special presentations to showcase particular improvements, outcomes or monitoring mechanisms or to highlight areas of risk and concern.

Despite these potential advantages, many participants expressed reservations, amongst them one peer reviewer, who experienced generally more positive assessment results in announced inspections. Several NHS managers argued that the inaccurate depiction of the real situation could generate 'a false sense of security' amongst senior managers, who miss the opportunity to learn about and from the identified shortcomings. Participants substantiated their reservation or suspicion concerning announced inspections by arguing that it was human nature to prepare for an inspection and instanced several examples of potential preparations. These might include, for example,

- deploying more staff or more skilled professionals on the inspected ward
- informing, sensitising or instructing staff
- preparing the paperwork and 'anything that might not be up to scratch'
- shifting temporarily more material resources, such as pillows or drips, onto the ward and
- generally sprucing up the ward.

Nonetheless, some participants argued that an announced visit with a robust inspection methodology would detect persistent shortcomings.

'If a ward is truly failing, you can't hide that. Even if you know about, even if there is a known inspection, you can't change that data. [...] Doesn't matter if people know you are coming or not. If you have the right assessors, in my opinion, with the right assessors, trained properly, and the right tool to look at, you can go, even if they know you are coming, and still find issues. You can't hide them if they are truly there.' (IN44)

Some NHS executive managers reported about HIW inspections, which they or their LHB had requested. According to the research participants, the triggers to invite HIW or other external experts can be

- internal, such as

'a feeling that something wasn't right' (IN16),

or

- external, such as

'a very significant high-profile complaint' (IN27).

The managers explained that they commissioned independent experts due to a lack of specialists inside the organisation, distrust or a perceived business myopia. The external experts are expected to help the executive managers by verifying or refuting the existence of a problem, by analysing the problem and by preparing recommendations.

Some participants stated that they would like to invite HIW to conduct announced inspections at a particular ward. Other managers referred to previous or ongoing arrangements with the Community Health Council or the Royal College of Nursing to conduct unannounced visits at a particular site following complaints from patients or staff.

5.3.3 Inspection methods and tools

Many participants compared the DECI with the Trusted-to-care spot-checks, stating that DECI themes were very similar, but DECI methods and tools are more sophisticated. According to one participant the Trusted-to-care spot-checks looked at the nurses' documentation but did not review patient notes or medical documentation. Participants from independent hospitals noted a lack of coherence in how different review bodies expected hospitals to present documents and evidence. Other participants criticised HIW's focus on the process of care, rather than outputs and outcomes.

'They wouldn't necessarily know whether or not on this particular ward we are killing people. [...] they don't ask us for mortality data for that ward or that consultant. [...] they gather from the health board no intelligence to inform the visit.' (IN27)

Some interviewees noted that HIW increasingly checked the staffing levels (= input) of the inspected ward. One participant advised caution with the reliance on nursing documentation, instancing the case of a patient's nutritional assessment sheet that was meaningless because it was incorrectly filled in.

Although some NHS participants mentioned that the inspection team 'looked at the environment' during DECIIs, this seems to be more prevalent in independent hospital inspections. Many participants with experience as reviewers in internal or external inspection schemes maintained that their professional expertise and their olfactory and audio-visual senses helped them to spot problem areas. Although several interviewees declared that they were able to identify, whether a ward was run well or not, based on their first impression, none of them suggested relying on intuition only. There was, however, some contraction amongst nursing managers.

'When they did the unannounced visit, they were here for a couple of hours, looking at medicines, and looking at a few case notes and things. And I don't think you can say that's completely representative of all the care given. [I recommend] just spending longer and observing. For me, there is something about the mystery shopper type scenario. They come in, and it's truly unannounced. [...] I really do like the idea. I would welcome anyone coming in to one of our, obviously you couldn't go into the clinical area. But things like out-patients, and you can get a feel. I truly believe that, within five seconds, you can smell and feel it. (IN26)

One NHS participant argued that individual patients' views were subjective and not necessarily representative, referring to a meal that a patient considered as cold. Another participant wondered how authentic the information from inpatients was, given that inpatients tend not to complain while being treated at the hospital.

NHS managers perceived HIW's questionnaire for structured staff interviews as very detailed. One participant criticised that her staff were asked leading questions.

some of the questions have asked our staff, can be very leading. "So, it looks as if you're short of staff. Are you?" [...] And... to some degree, there have been times, when people have been... "Tell me, is there something you want to share with me, that you are concerned? Because we can tell management to sort it" (IN46)

Several participants stated that their staff sometimes volunteered information to the inspection teams. From an inspection report, one NHS manager deduced that the ward sister had confided in HIW.

'I know that there was one thing fed back, that was her [ward sister's] manipulating. Which is fine, because I tried to get money for it. And it was very interesting that she must have done that independently.

Because there is no way they would have identified that, unless somebody pointed them in that direction.’ (IN37)

Several participants noted that frontline staff often felt uncomfortable about being interviewed due to their lack of experience. One interviewee stated that particularly junior nurses, who do not have the full overview, tend to be rather negative in their views. Another interviewee described a rather comical situation, when a nurse after her return from a long period of absence was interviewed about the hospital’s improvement activities.

‘[HIW] ask her about transforming care and dementia, and she said “I don’t know what you are talking about, we don’t do any of that here”. [...] she was on the ward, it was like her second day back from maternity leave and... they took it to one side and... she might as well have stabbed me in the back [...] ‘if they had asked anyone else who was on duty, it would have been absolutely fine. (IN15)

Many participants critically commented that the DECI team predominantly interviewed nurses. Yet, some participants had noticed a wider range of interviewed staff in the second half of 2014, including support workers, domestic and catering staff, physicians and pharmacists. Several participants regretted that HIW aimed to minimize the interaction with senior managers during the inspections. They argued that interviewing senior managers would help the inspection team to understand the ward management and prevent them from forming wrong assumptions.

Some few senior managers stated that they had approached the inspection team to convey a positive image.

‘I felt I had to go in and really shine a light on the positives we were doing. [...] On this occasion, I deliberately went and intercepted them before lunch. And I dragged them around to areas that I thought we were doing, you know, “I want to show you this because this is a project that we are doing” and they were “Oh, gosh, we didn’t realize that.”’ (IN37)

Similarly, another participant proposed dedicating ‘quality time’ for interviews with senior managers to learn about ongoing improvement activities. The interview of one NHS manager at directorate level during a hospital inspection in 2015 indicates that HIW had changed its previous practice.

Many NHS and independent managers stated that they were neither given nor shown the inspection tools.

‘If we are going to have true transparency, we should be able to understand: “what are the standards?”, and how are they measuring us against those.’ (IN27)

One NHS participant explained that she had encouraged her staff to become HIW peer reviewers and thus get access to HIW's assessment criteria and tools. Two NHS managers stated that the DECI tools were currently used in the internal inspection schemes of their LHBs. Two peer reviewers were convinced that the tools were still publicly available on HIW's website, although they were not.

'They [tools] are all on the website. So, the methodology about how the tool was written. And the tool was available on HIW's website and all health board had access anyway. It was allowed to share that detail.' (IN44)

Another peer reviewer added that infection control nurses in the healthcare organisations were familiar with the ICNA¹⁷ audit tool, which was adapted and applied in HIW's cleanliness spot-checks.

5.3.4 Inspection team

Healthcare managers shared HIW's view that inspections should be conducted by a multidisciplinary team with relevant competencies, emphasising particularly the importance of appropriate clinical expertise. One participant criticised the ineptitude of CQC's generic inspectors.

'They [CQC] didn't have specialist inspectors as part of that inspection. No. ... So, in fact they gave us a clean bill of health on infection, for barring a few minor, minor issues. Whereas actually, we knew internally and reporting to our board that there were some more major things that we needed to deal with.' (IN3)

Independent hospital managers positively portrayed HIW's inspections and inspection teams as objective, fair and balanced, professional and very courteous. Independent managers acknowledged the scrutiny of HIW's inspections and valued the professionalism and commitment of the HIW's inspection manager, who has been in this position for many years. Explicitly, they expressed respect for HIW's inspection manager, who remains at the inspection site, until an identified issue is tackled, and who urges HIW's head office to fax immediately a management letter.

Due to their limited exposure, NHS managers were generally less explicit about HIW review managers. They reported about their different experiences of how individual HIW reviewers perceived their role. Experiences varied from 'an inspector who is very rigid and punitive' to another, 'who is trying to help make things better'. One participant experienced a non-confrontational, but professionally challenging behaviour as supportive and effective in the Cancer-peer-reviews. Participants stated that the quality

¹⁷ Renamed in 2006: Infection Prevention Society (IPS).

of HIW inspections in the NHS varied depending on the particular reviewers and their level of expertise. One NHS interviewee positively noted that HIW had addressed the 'lack of clinical input' (Royal College of Nursing, 2013) by recruiting peer-reviewers with a clinical background, yet another NHS manager reported about HIW using retired peer-reviewers.

'Some of the people who assess, may have not have been in clinical practice for quite some time, and therefore the ability and the realism is not always there.' (IN45)

Therefore, some NHS participants wished to receive more precise information about the professional expertise of the reviewers.

'It would be quite helpful if they said in their reports, who comprised the teams, actually.' ... 'it provides a level of assurance to the public as well, doesn't it? About how many people came in, who they were, what their backgrounds are.' (IN29)

Healthcare managers expressed their appreciation for reviewers, who are experienced specialists in the relevant field. In this regard, some participants preferred the Trusted-to-care spot-checks, whose reviewers were practicing clinicians or very recently retired, and/or the independent Cancer-peer-reviews.

'The difference here is, the people who are asking them, interviewing them, looking at their service, are experts. They run those services themselves somewhere else in the country. So, where there is a long waiting list for... breast cancer treatment for example, you would have a breast oncologist sitting there, and a specialist nurse sitting there, who says "what are you doing about these waiting lists? What impact is that having on outcomes?" Getting to the bottom of where things are not absolutely clear in what the team is submitting. So, I've been part of the training for that. And we did role play. So, what's it like being inspected or peer reviewed, and what's it like to be the reviewer.' (IN19).

NHS managers particularly appreciated HIW's cleanliness spot-checks as valuable and effective due to the peer reviewers' expertise in infection control. Several interviewees opined that peer reviewers needed to be familiar with the healthcare standards and practices in Wales. Opinions on what constituted the right expertise sometimes varied amongst the interviewees and were sometimes controversial: while two NHS managers complained about the ignorance concerning 'how our systems work across Wales' amongst particular expert-reviewers from England and Scotland, whom HIW had recruited previously, a senior manager of the same LHB suggested recruiting expert-reviewers from England, since there were not sufficient experts in Wales in certain fields. As an alternative to HIW's current approach, one NHS interviewee proposed a rotation

scheme by which clinical specialists would work for a fixed period as review managers at HIW's head office.

Some independent participants highlighted the need for reviewers to understand the context of the independent sector. Similarly, some NHS managers argued that the reviewers needed to be familiar with the NHS.

'I think one of the things with the inspection teams is, you need somebody on there, with experience of the independent hospitals. [...] from individual inspectors [peer-reviewers], who have had no experience or contact particularly with the independent sector. There has been a degree of bias in the past.' (IN25)

Conversely, a reviewer, who was described by an independent manager as particularly dogmatic, had private sector experience.

Like HIW, healthcare managers positively judged the double role of peer reviewers, which 'increases skill and knowledge on both sides' and through the exposure to different clinical practices enables them to compare and challenge poor practice in their own organisation. Peer reviewers noted a change in their own attitude towards inspections and quality improvement. Given the above, several NHS participants called for more peer-review schemes, similar to the Cancer-peer-reviews, to promote learning across healthcare organisations.

Many participants stated three people as adequate size for a typical hospital inspection, yet some acknowledged that the ideal team size and composition depend on the purpose of the inspection and the inspected site. NHS managers noted that the DECI teams increased from three members prior to 2014 to four and more since then. The team size also varied in independent hospital inspections: while one participant noticed an increase from two or three to 'between four and six people', another participant counted only two people in an HIW inspection in the same period.

Some NHS hospital managers raised concerns about large teams, though opinions differed concerning how many team members were too many. Interestingly, one manager did not take offence at six people, particularly, because HIW had explained and apologized for the larger size. With her experience in the independent Cancer-peer-review programme, another NHS participant considered four to six inspectors as the 'minimum size'.

Participants argued that massive inspection teams generally could or did disrupt the care process and distract frontline staff. To minimise the disruption, one interviewee suggested splitting up the team to visit two wards. Another participant acknowledged HIW's existing efforts to reduce the stress levels of nurses.

Many participants argued that the inspection team needed to comprise at least one member with clinical experience and a specialty corresponding to the inspection theme. Suggestions were made concerning the participation of other clinical professions, as with physicians, physiotherapists, pharmacists and geriatric nurses. Participants argued that their non-representation in the inspection team allowed medical professionals to distance themselves from HIW's inspections. Referring to the Cancer-peer-review programme, one interviewee emphasised that peer-to-peer inspections are more likely to be accepted amongst the medical profession.

Some participants used the term 'lay reviewers' in two different ways, referring either to HIW inspectors without a clinical background or to external lay reviewers. The role of HIW review managers without a clinical background seems to amalgamate with that of the lay reviewer.

Most participants appreciated the involvement of lay reviewers, particularly due to

- their different perspective and experience as (potential) service users
- their ability to enter a more informal dialogue with patients and relatives, and thus gather more genuine information and
- their lack of clinical knowledge and thus their tendency to question established practices and behaviours.

This also applies to the Cancer-peer-reviews, which recruit from the same pool of lay reviewers.

'The ones [lay reviewers] I worked with were spot on and had an understanding of the context of the Welsh NHS. [...] I think ... certainly there needs to be the confidence to dig a bit deeper. Not to accept the first response. To keep digging. But also have the ability to be pleasant, and articulate, and not... it's almost like encouraging a response, rather than actually... requesting or challenging.' (IN28)

Despite predominantly positive narratives about 'really good' lay reviewers, a few participants suspected the motivation of certain lay reviewers. One interviewee, who had worked for the Trusted-to-care spot-checks, which did not comprise lay members, wondered whether HIW's lay reviewers truly represented the patient population, arguing that some lay reviewers were retired nurses, and suggested instead a closer cooperation with Community Health Council. Conversely, another NHS participant stated that amongst Community Health Council reviewers were some retired nurses.

5.4 Post-inspection

The findings presented below refer to the components and activities within the inspection process, which take place after the hospital has been inspected. This relates to the (i) immediate feedback, (ii) inspection reports and their publication, (iii) action plans, (iv) follow-up and (v) enforcement. These components are supposed to inform the relevant stakeholders about the degree of compliance with regulations and standards and, if necessary, enforce the corrective actions.

5.4.1 Immediate feedback

In general, healthcare managers appreciated the debriefing at the end of the inspection as an opportunity to

- (i) Familiarise themselves with the findings and ask for more detailed information,
- (ii) Explain and clarify possible misunderstandings or inaccuracies,
- (iii) Provide contextual information, e.g. about ongoing improvement activities,
- (iv) Discuss and challenge the relevance and substance of findings and legitimacy of conclusions,
- (v) Exchange views about corrective actions.

The overwhelming majority of interviewed managers had personally attended HIW debriefings. Yet, many senior NHS managers pointed to practical impediments for attending the debriefings of unannounced inspections, such as tight schedules and far distance. Independent hospital managers stated that they use their 'record of absolutely every remark' which the inspectors made during the visit and at the debriefing, to be able to act upon the oral feedback promptly, ideally on the day of the inspection. Also, several NHS managers mentioned taking notes during the debriefing. They explained that the notes helped them to establish the discrepancies between the debriefing and the later report. Often, participants experienced more positive statements in the debriefing than in the later reports.

'The feedback that we had, which was really fantastic feedback, it was absolutely fabulous, we were glowing after it, all of my staff, it was in one of our hospitals, [wards]. But there report, bore no resemblance with the fabulous feedback', but 'looked like a different report.' (IN24)

In contrast to some of HIW's reports, one NHS participant praised the Trusted-to-care spot-checks for their constructive verbal feedback, that 'matched the report'. While some participants explained the absence of praise in HIW's reports with HIW's general caution, others related the discrepancies to HIW's personnel changes and the large time gap between the inspection and the report. To prevent disappointment amongst hospital staff,

one manager suggested forewarning the audience during the debriefing that the praise will not 'appear in the report'.

Many healthcare managers acknowledged that the inspection teams generally tried to present 'good and bad' findings during the debriefings.

'It's a bit of an ordeal, always been told where you could improve things. But they usually give lots of positives as well. So, they don't just look at the negatives. And that is really helpful.' (IN35)

However, participants also noted a tendency for peer reviewers and the audience to focus on negative findings. Several interviewees considered those inspections useful and thus effective that compare the inspected body against other organisations and steer the inspected body with feedback about good practice. According to one participant, positive feedback from reviewers helped to positively influence the attitude of frontline staff towards inspectors.

'I felt very proud. We had the chief executive sitting there. These are issues that are largely to do with nursing, so it was a great experience. Also, for the [title] nurse, who runs the [specific] program here, I invited her to the feedback, so that the chief could see all the fabulous work that she and the team were doing' (IN19)

Only one NHS participant noticed that HIW had overlooked critical data during an inspection:

'I was expecting very different feedback, [...] when I heard they were in this particular ward. [...] I suppose it depends on how they triangulate the information. [...] The information was publicly available, and there were a few indicators that were publicised on a board inside the ward, that would have also been pretty obvious.'
(IN46)

NHS participants mentioned the frustration they felt, when inspections repeatedly criticised issues that they had no control over, such as the storage capacity or the layout of hospitals. Some interviewees wondered whether the expectations of the inspection team were always realistic, instancing examples of criticisms such as patients helped fellow patients during meal times and not every patient's room had a clinical sink.

One manager, who challenged findings and added contextual information, appreciated that initially incorrectly interpreted data and vague or unrealistic oral recommendations did not find their way into the later report. Healthcare managers stated that they wished to understand the justification for the findings and proposed actions. Some participants noticed a variation amongst individual reviewers and instanced cases, where single findings were generalised and not sufficiently substantiated.

Several participants recognised the difficulty, especially for junior reviewers, to provide feedback to top and senior NHS managers. In this regard, one NHS manager noticed an improvement in the leadership in the inspection teams. One peer reviewer found it more effective when a peer reviewer instead of a review manager without clinical background presented the findings.

Several interviewees reported about inspections which imposed immediate corrective actions on the hospitals as a difficult and upsetting experience. NHS and independent managers stated that they would take major concerns seriously and act upon them immediately.

5.4.2 Reporting

In the interviews, HIW's reporting was by far the most criticised component in HIW's inspection regime. Almost all healthcare managers complained about the severe reporting delays in the preceding years. Moreover, some HIW inspections in 2012-13 never generated a report and one report of an HIW inspection in 2013 appeared to be temporarily lost at HIW's head office (a phenomenon, which another NHS participant stated she had experienced previously with CQC). As the situation at their hospitals had allegedly changed after the inspection, many participants considered publishing severely delayed reports as 'almost pointless'. They criticised that outdated reports created a false impression amongst the public and undermined the morale of the hospital staff.

Conversely, one NHS manager very optimistically concluded from the absence of the report that the inspection results must have been positive, otherwise HIW would have raised concerns 'at the time'. Independent managers explained that the delays of positive inspection results, which were to inform the hospital's performance management, caused frustration.

We did get our report. [...] It was an amazing report, which was duly deserved, but it sort of lost its momentum because it lost its momentum because we waited so long for it. (IN1)

Several healthcare managers perceived severe delays as disrespect and/or a sign of a dysfunctional inspection regime, which, as they said, undermined HIW's credibility. Participants associated the delays and the low frequency of inspections with HIW's capacity problems in 2012-2014. One interviewee blamed previous 'weaknesses in the second layer' of HIW's organisational structure for the temporary difficulties. Others, however, noted that timeliness had always been a problem.

During 2014 and 2015, several healthcare managers noticed a significant improvement in the submission of HIW reports, but some draft reports were still overdue.

Healthcare managers valued the opportunity to check HIW's draft inspection reports for factual accuracies as 'good practice'. Opinions amongst the participants differed regarding the prevalence and significance of inaccuracies. Several interviewees considered the inspection reports 'in the majority of cases' as accurate and sufficiently substantiated, though often lacking precision in certain details. Some participants interpreted previous inaccuracies, poor English grammar and style as a lack of professionalism, which in their view undermined HIW's credibility. Other participants considered HIW's refusal to dispute factual findings as adding rigour and credibility to the inspection regimes.

Reportedly, it has not been unusual for healthcare managers to go beyond mere accuracy checks, by commenting on perceived misinterpretations, adding contextual and explanatory information and suggesting textual changes, which HIW in several cases accepted.

One independent manager explained previous errors and omissions with the large time-gaps between the inspection and report-writing and expressed full satisfaction with the timeliness and objectivity of reports in 2014. In contrast, an NHS participant related the severe and frequent factual inaccuracies in CQC's previous draft inspection reports to 'a lack of understanding' amongst CQC inspectors.

Some participants were sceptical whether the population was aware of HIW and its inspection reports. Due to the lack of direct feedback from patients, most hospital managers did not know and/or doubted that many patients read inspection reports or respective news. One peer reviewer noted that many relatives had asked during the inspections for the publishing date of the inspection report, which she was unable to announce given HIW's notorious reporting delays.

Healthcare organisations typically cascade HIW's inspection reports down from the board members and senior nurse teams to the quality and safety committee and the patient liaison group. Two interviewees commented that frontline staff might be too busy to read the full inspection reports and therefore proposed short summaries.

One participant critically noted the lack of a mechanism, by which LHBs are early and proactively informed about poor findings of inspected healthcare providers in Wales and England. Not many interviewed managers had actively searched and read HIW's inspection reports of other LHBs. Most participants stated reading reports sporadically, when they learnt about particular inspections from other colleagues or the media. Amongst NHS managers, LHB nursing directors appeared to be the most familiar with

inspection results of other LHBs due to their peer-group networking and their motivation to learn from poor or best practice.

'We have a nurse here [...] and she does read the inspection reports of other organisations, to see if there are common themes or anything that we can learn.' (IN29)

Some participants noticed and welcomed particular changes in the structure and format of HIW's recent inspection reports. A few participants suggested reintroducing a traffic-light assessment system, referring to the perceived advantages, such as: giving a message, which is easy to understand for non-professionals, highlighting strengths and weaknesses, and facilitating benchmarking and monitoring over time and across LHBs.

Other participants pointed to the weaknesses of such a reductionist approach, if applied without differentiating between hospital areas. Many managers stated that they would appreciate Wales-wide benchmarking, informed by a comparison of self-assessments and inspection reports, using the healthcare standards as a framework.

Some interviewed healthcare managers interpreted inspection reports quantitatively, including one participant, whose hospital allegedly 'scored the highest' in the 2014's Trusted-to-care spot-checks, which is surprising, since the reports do not contain scores. Another participant interpreted her DECI report as 'very good'.

High-level LHB managers appreciated HIW inspections as a means to inform them, whether LHB policies, such as hand-hygiene and incontinence, were implemented. Participants referred to various sources, which they use to cross-validate findings, since inspection findings and conclusions sometimes differ across review bodies. Two members of the same LHB stated that HIW reports in combination with similar recommendations from other organisations were instrumental in convincing a particular staff group of necessary changes.

Though NHS managers considered most of HIW's recommendations 'reasonably sensible and straightforward' and 'practical', one NHS participant strongly criticised HIW's recommendations as based on the subjective view of a reviewer and not current best practice; idealistic and not feasible given the current infrastructure and lack of resources; vague and not specific enough; and too many and not risk-assessed/prioritised.

The same participant stated that 'timeliness, credibility, objectivity, based on standards, consistency' of inspection reports would increase the LHB's ownership and thus the effectiveness of HIW's inspections. To support the corporate risk management,

healthcare managers proposed that HIW should differentiate within the findings between major, systemic issues and insignificant, one-off issues.

Participants generally acknowledged HIW's intention to produce balanced reports and opined that the media are 'not particularly interested in good reports'. Nevertheless, NHS managers predominantly commented on negative inspection reports and the very 'demoralising' effect on frontline managers and staff. Participants explained that staff and managers felt powerless due to their limited managerial control over financial and human resources.

'The clinical leaders are under the most incredible pressure. That they can't win, can they? They are in a sandwich position. They have the pressure from the team and the patients, you know, the clinical floor. And then they have the managerial pressure. And you almost have sideways pressure as well. So, they are completely sandwiched. We say we want to empower them, but actually we disempower.' (IN37)

Other NHS participants confirmed this by explaining that negative inspection reports typically trigger further investigations and actions from the top management. Some healthcare managers reportedly comforted and encouraged their staff to constructively deal with HIW's criticism. Participants argued that when staff understands the justification of HIW's criticism, they comply more readily with the corrective actions and thus HIW inspections become more effective. One NHS manager described her repeated efforts to convince the senior nurse and the ward sisters that HIW's inspection report was 'very good'. She suspected that the misinterpretation resulted from both, HIW's focus on negative findings in the report and the staff's distorted perception.

Some participants described the preventative effect that negative inspection results can have on other healthcare organisations, highlighting the role of media, such as television, newspapers and photographs in HIW's cleanliness spot-checks. The latter were, according to one peer reviewer, taken seriously from the beginning due to the involvement of the Welsh government and the immense media attention on the very first inspection in an NHS hospital. NHS participants stated that they felt 'disappointed, upset, anxious' and 'embarrassed for' the staff of the exposed hospitals. The anticipation of reputation-damaging inspections reportedly motivated some managers to introduce their own internal inspection schemes.

'I think what was very effective, there was a time when they [HIW] were doing the cleanliness inspections, when... what they did was name and shame. They photographed evidence. That was very powerful. And... I personally wasn't subjected to... it was another health board. And, my God, I felt embarrassed for them. And certainly

it helped motivate us to do our own name and shame spot checks.'
(IN37)

One NHS participant described that patients became frightened after a prominent person had publicly named and shamed her LHB. On the request of the manager, HIW paid an unannounced visit to the hospital thereafter, but the LHB could not refer to the inspection report. The manager seemed very mature and professional in her reflection about the case.

'[...] the [ward] report published, which HIW did, nobody knows [...] that that was the ward. [...] we are not allowed to publicly respond, because it would be breach of confidentiality. So, it is a very difficult position to be in. But, she [the person who made the allegations] is the best thing that has happened to me. Because she sits on my shoulder. And every time [...] I think about what we are going to publish in the public domain, she is there, nagging me, saying "What would she say if she saw this?" And actually that is very helpful, because... we have to be able to suffer the scrutiny of our public. That's our duty, we are public service. So, if we don't have an investigation team, that is challenging enough, and therefore publishing our reports so we improve the standard, then something is not right.' (IN27)

As a reassurance to the public, some NHS participants wanted HIW's reports emphasise positive findings. Healthcare managers reported about publicising positive HIW findings for public relations purposes.

Also, independent managers regarded the publication of positive findings as excellent for managers, staff and the business. Though, they did not consider HIW's inspection reports decisive for their clients' ultimate choice but reassuring as an independent source of information. Many participants assumed or had experienced that positive inspection reports positively influenced staff morale. Some healthcare managers stated that they tried to reinforce these feelings in their oral and written communication with the frontline staff.

'We do celebrate our successes, very much, with the staff.' (IN25)

One NHS participant criticised that the HIW inspection reports did not facilitate learning from best practices.

'It's very difficult to get from the report what are the best practices.'
[...] if we wanted to do this from a learning and improvement perspective, it [HIW report] does not say what areas of a board are good at'. (IN46)

5.4.3 Action plan

At what time NHS organisations generate an improvement plan seems to vary. While some healthcare managers stated that their organisations usually acted upon feedback straightaway after the inspection and/or drafted immediately an improvement plan, other participants explained that their organisations waited until the inspection report arrived or was agreed. The rationale for the latter were potential discrepancies between the verbal feedback and the report, disagreements about whether HIW's recommendations were feasible, and the necessity to base the allocation of financial resources for the improvement plan on an official document. Participants agreed that HIW's severely delayed reports should not serve as an excuse for not acting upon oral feedback. Some managers complained that HIW required the LHB to submit an action plan based on HIW's outdated report, even though the original recommendations had become 'irrelevant'. This demand appeared unreasonable and not contributing to regulatory effectiveness.

Many participants considered the response time of one week that HIW allows for submitting the draft plan as insufficient to involve internal stakeholders. They emphasised the importance of involving frontline nurse managers to create a sense of ownership, thereby enhancing the implementation of improvement actions and thus the effectiveness of the inspection regime. One NHS manager explained that she circumvented the problem by producing two versions of improvement plans: one concise plan for HIW and another more detailed for internal use.

Hardly any of the respective NHS managers had noted before the interview that HIW had not always published the improvement plans with the DECI reports. After realising, they criticised that the omission potentially casts a bad light on their LHB. A practical solution could be, as one NHS manager proposed, an online database, which allowed LHB's to upload and update improvement plans.

Several NHS managers complained in 2014 about the time and resources required by the numerous action plans in the wake of internal and external inspections. Participants deemed that these resources would be better invested in executing the plans, solving problems and delivering healthcare. The mere existence of improvement plans does not guarantee implementation, particularly when not sufficiently followed-up.

'an action plan doesn't make change happen. [...] one of the things that really struck me in the Mid Staffs reports was, there's hundreds of action plans within the NHS. Hundreds. But that isn't what effects change. And that isn't ever checked.' (IN26)

5.4.4 Follow-up

Many NHS participants considered external follow-up visits and accountability mechanisms necessary, irrespective of the LHBs' internal monitoring and submission of progress updates to HIW. Numerous NHS managers expressed their dissatisfaction about HIW's rare or inconsistent follow-ups in the past. Although they emphasised that their organisations implemented the action plans, poor follow-up was regarded as potentially undermining the effectiveness of HIW's inspection regimes.

None of the interviewed independent managers had personally experienced an intense follow-up scheme, such as the respective HIW manager described. However, independent hospital managers were convinced that HIW would keep coming back, until a severe issue was resolved. Two independent participants recalled follow-up visits of their hospital within a month in 2012 and of another hospital in 2014.

'[HIW's lead inspector] exercises sensible judgement about what she considers to be a risk and the purpose of her role is to keeping patients safe, not just ticking a box, because it says it in the rule book and then applying a judgement to whether she feels confident that the hospital is going to address that risk in a timely fashion. [...] So there has to be a mutual sense of trust. And I respect the fact that she uses that judgement wisely, and I don't abuse that. We don't abuse that trust.' (IN7)

5.4.5 Enforcement

Many NHS managers expressed their preference for a powerful inspectorate and 'a robust process by which health boards are held to account'. Opinions differed concerning the need to grant HIW (more) regulatory powers over the NHS. Several participants considered HIW's existing powers sufficient. One manager referred to a Cancer-peer-review, where HIW's lead reviewer threatened to close the section¹⁸.

'the HIW guy said: "You've got one week to put that in place or we will close you down." So, I was really amazed that, it all seems very, very friendly, and everyone was being very professional, but this [HIW] is a tiger with teeth. It actually means something.' (IN15)

One healthcare manager wondered whether HIW was not 'allowed' to utilise its existing powers more often. Likewise, another participant instanced several NHS trusts in England, where CQC should have taken more rigorous and rapid enforcement actions to support the population in the catchment area.

¹⁸ Until 2016, HIW supported the Cancer-peer-review programme with guidance, reviewers and organisational arrangements.

Some NHS managers had experienced interventions by the government, subsequent to HIW's critical findings. In one case, the government's reaction was induced by an internal paper on the follow-up of an HIW inspection, which 'leaked to the press'.

'We are obviously agents of Welsh Government, and therefore they will, if there is a series of critical reports, [...] be looking at different performance and accountability arrangements within the board or different escalation or looking at different levels of assurance as parts of the system.' (IN10)

One independent manager highlighted the positive impact which the public debate on NHS failings had on NHS managers and thus on the effectiveness of HIW's inspections.

'If you're an NHS manager now, in light of Keogh and Francis, you would absolutely want your NHS to look as if it had implemented and built its NHS services on the recommendations.' (IN1)

5.5 Wider impact

Interviewees stated that a systematic, external inspection with a multidisciplinary team could help the healthcare organisations to identify problematic areas and result in a 'lot of learning'. However, participants could hardly instance any examples, where HIW inspections had detected substantial problems that they had not identified already. Usually, healthcare managers stated that the inspections spotted minor issues that they were not aware of, brought up issues that they knew already and were working on, and/or raised the priority of issues that had been given low priority by the healthcare organisation.

Results of independent hospitals inspections are in general more positive than those of NHS hospitals. It is, however, not clear how far these differences can be directly attributed to HIW's inspection regime. Independent managers mentioned several factors, which allegedly drive compliance and high performance in their hospitals. Positive factors included the commitment to clinical excellence and patient orientation amongst many independent providers, appreciation of HIW's advice on best practice, the different clientele and resources and a positive attitude towards inspections. Negative factors were the fear of independent hospitals losing their licence and the competitive environment, in connection with concerns that negative publicity could affect reputation.

The latter was also mentioned regarding the cancer network, where one peer reviewer recognised healthy competition amongst the LHB. Cancer-peer-reviews were generally perceived as successful in driving improvement and promoting best practice, particularly due to peer pressure mechanisms and peer reviewer training.

'There was a serious concern that we need another [specialty] nurse. So, I've been part of helping put together the business case in order to approach our managers just to say "actually, with the number of [type] cancers we are not meeting the commitments of, say, even giving all of these patients a key worker". 'So, that's been as a direct result of peer review.' (IN15)

Conducive factors seemed to be the small community of cancer specialists in Wales (who know each other) and the particular setting (a network with a small, well-managed NHS trust in its heart).

Many NHS participants recognised a positive impact of HIW's inspections, describing external inspections as a lever for change and instancing improvements concerning factors such as estate/infrastructure resources, staffing levels, and pathways of care.

Hospital managers explained that HIW's authority as an impartial, regulatory body and its formal and systematic inspections provided evidence and validation, which added 'extra credibility and weight to an argument' and convinced the decision-makers to release funding or particular stakeholders, such as consultants, to accept changes in the healthcare process. The participants confirmed that HIW's findings and recommendations had helped to effect positive changes in hospital care.

A peer reviewer assessed HIW's former cleanliness spot-checks as very effective in improving the hospital environment and patient experience. The cleanliness spot-checks reportedly gave the environment committee 'the stick' to argue for more environment and infection control measures. Over time, however, the cleanliness spot-checks seemed to have lost their impetus.

'There had been little or no investment in patient environment, which was then impacting on infection control. So, they [cleanliness spot-checks] were absolutely right for the time, and I personally feel that they made a huge difference in improving the environment for patients, not just from an infection control perspective, but from privacy and dignity perspective.' (IN43)

Some participants instanced cases, where they or other staff had deliberately tried to influence the inspection team to investigate an area. Participants especially appreciated the impact of HIW's inspections, after their own efforts to effect change remained unsuccessful. This, however, made them realise their own lack of power and the perceived unnecessary delay. For example, in one case the executive managers, who had rejected the appeal that one participant had previously made for funds, pretended not to have known about the storage shortage prior to HIW's inspection. In another case, the infection control nurses had been advocating for more attention and investments

without success, because ‘infection control wasn’t as high on the agenda as it should have been’ and as it became through HIW’s spot-checks.

As several participants explained, NHS nursing directors do not necessarily have direct financial responsibility, yet, a ‘very strong individual’ can influence decisions. Two peer reviewers emphasised the central role of leadership, support and ownership for the effectiveness of external inspections. Several participants asserted that HIW’s recommendations have influenced decision makers to redefine priorities and mobilise unscheduled funds, such as ‘end of the year money’ and ‘charity funds’. While one participant with a nursing background complained that sometimes

‘professional ethics are compromised by the financial [...] management decisions’, (IN22)

another manager without nursing background explained:

‘You can’t spend a million pounds in a building that is only worth half a million pounds.’ (IN40)

Some managers instanced examples of HIW’s recommendations with questionable cost-effectiveness, such as

‘televisions for an area that shouldn’t have televisions’ and ‘hot food in an A&E department’ (IN42)

Several participants pointed to the financial constraints and low staffing levels as underlying causes of the problems in the NHS and argued for interventions and change at governmental level. Participants from three NHS organisations provided different explanations on why they had not solved the problems prior to the inspection:

‘we are not strong on identifying areas of concern, addressing them, learning lessons, spreading that across and stopping that from happening again.’ (IN23)

‘they [HIW] did come back with some very good comments. Very, very positive feedback, and actual fact. And some things that we felt were relevant comments to make, and things that we worked towards. Things like, what I talked about, related to the estate as a matter of fact. And those sorts of things are helpful for us, in order to try to get capital, more capital money from Welsh Government.’ (IN32)

‘I value other opinion for the very reason that we do become desensitized, and think you see things that perhaps others don’t. So, I do think inspections are important.’ (IN31)

Some NHS participants referred to Mid Staffordshire and/or questioned why HIW had not flagged up the issues at Abertawe Bro Morgannwg (Andrews & Butler, 2014) and

Betsi Cadwaladr (Wales Audit Office & Healthcare Inspectorate Wales 2013) earlier. One peer reviewer, who recognised achievements at the Princess of Wales hospital through the Trusted-to-care and the DECI, wondered whether the identified problems (Andrews & Butler, 2014) could have been prevented by regular, proactive inspections.

5.5 Conclusion

The interviews with healthcare managers indicated that HIW's inspections can and have effected improvement. The extent of compliance with standards has varied across different inspection regimes and hospitals and healthcare improvement is generally moderate. HIW's inspections appeared to be instrumental in detecting and raising awareness for non-compliance issues, triggering or changing the priority of improvement actions. The inspections were particularly valued by independent hospitals for allowing them to share advice on best practice beyond mere compliance.

Differences between large NHS healthcare organisations and the small independent hospitals are evident. They concern not only ownership, funding and size, but typically also the scope of managerial responsibilities, customer-focus and individual attitudes. Despite these general factors, variability exists in the performance and thus inspection results across different wards within the same (NHS) hospital.

Variability also exists and is unavoidable across HIW's inspections. NHS inspections especially are conducted by different teams comprising review managers with or without a clinical background, and peer and lay reviewers with different expertise and experiences. Contrary to their NHS colleagues, independent hospital managers rarely highlighted shortcomings prior or during the inspection. Independent managers seemed keen to exceed the required standards and benefit from HIW's expertise.

Problems that many NHS and some independent managers referred to mainly related to the pre- and post-inspection process. This included

- (i) Occasional disagreement in the interpretation of healthcare standards deriving from the generic nature of healthcare standards and the resource limitations of the healthcare organisations.
- (ii) HIW's perceived withdrawal from reviewing and validating the self-assessments.
- (iii) HIW's claim to apply a targeted approach in the selection of inspection sites, which may lead to the false assumption that hospital services are safe, because they are not inspected.
- (iv) Discrepancies between oral and written feedback, which undermined staff morale and the attitude towards inspections.

- (v) Severe delays in previous reporting and insufficient external follow-up, which could have delayed the implementation of corrective actions.

Table 6 provides a summary of the key findings from all the interviews with HIW and healthcare managers. It brings together the key points from chapter 4 (inspecting and chapter 5 (being inspected)).

TABLE 6 SYNOPSIS OF KEY FINDINGS

Key findings across the interviewed HIW and healthcare managers	Specific aspects and findings amongst particular interviewees
Standards <ul style="list-style-type: none"> The generic healthcare standards leave room for interpretation and thus potential disagreement between HIW and hospitals, particularly NHS. The involvement of healthcare managers in the development and review of healthcare standards has increased understanding and ownership of and thus compliance with healthcare standards – particularly in the independent healthcare sector. 	<u>Healthcare managers:</u> Particularly large NHS organisations struggle to deliver healthcare above the minimum standards.
Registration <ul style="list-style-type: none"> The close cooperation between HIW and the independent hospital managers has increased the understanding of registration requirements, mutual respect and thus compliance with requirements. 	
Self-assessment against healthcare standards <ul style="list-style-type: none"> The intended quality assurance / improvement through self-assessment by LHBs and external validation by HIW failed. Not all healthcare organisations are sufficiently mature to regularly and rigorously conduct self-assessments - without external quality control and feedback. 	<u>Healthcare managers:</u> HIW, with its limited resources, was overwhelmed by the workload. Healthcare organisations lacked guidance (from HIW). <u>HIW:</u> Healthcare organisations became complacent.
Selection of inspection sites <ul style="list-style-type: none"> HIW's resources are not sufficient to annually inspect all acute-care hospitals in Wales. HIW applies various strategies, criteria and sources of information to select inspection sites. Not all inspections are 'risk-based' or targeted. Although HIW's analytical capacity has improved, it is difficult to identify poorly performing wards. 	<u>Peer reviewers:</u> Self-reported data can be flawed and should therefore not be the only basis to select inspection sites. Access to ward-specific data would be important due to the variability of healthcare across hospital wards.
Frequency, duration and depth <ul style="list-style-type: none"> The small number of inspections in 2012-13 undermined HIW's reputation and effectiveness. Given its limited resources, HIW tries to strike a balance between the frequency, duration and depth of its inspections. 	<u>NHS managers:</u> Frequent, uncoordinated inspections with negative assessment results can frustrate and desensitize hospital staff (and managers), who feel powerless.
Inspection mode <ul style="list-style-type: none"> HIW's unannounced inspections are deemed to reflect a more authentic picture of the situation (than announced) and thus constitute a reality check for hospital managers (and HIW). 	<u>NHS managers:</u> Unannounced inspections are more disruptive (on the day of inspection) than announced inspections.
Inspection methods and tools <ul style="list-style-type: none"> HIW applies a mix of different methods and tools, this includes the use of including olfactory senses. 	<u>NHS managers:</u> Misperceptions have happened when senior hospital managers are not interviewed during the inspection.

Key findings across the interviewed HIW and healthcare managers	Specific aspects and findings amongst particular interviewees
Inspection team <ul style="list-style-type: none"> • HIW approach to use external peer reviewers and lay reviewers is one of HIW's major strengths. • (Peer) Reviewers with relevant up-to-date clinical / professional expertise add to the credibility of HIW inspections, the willingness to accept findings and implement recommendations. 	<u>Healthcare managers:</u> Misperceptions have happened because of peer reviewers without up-to-date clinical/professional expertise.
Oral feedback and immediate action <ul style="list-style-type: none"> • Findings and recommendations are more willingly accepted when substantiated and presented by an experienced team leader and/or specialist. • Oral feedback and management letters help the organisation to act quickly upon inspection findings. • Some managers, particularly from the independent sector, approach inspectors proactively for advice on best practice. 	<u>NHS managers:</u> Some NHS organisations start only taking corrective action upon the inspection report.
Reporting <ul style="list-style-type: none"> • Outdated reports, due to severe publication delays in the past, have undermined HIW reputation and effectiveness. • HIW has improved the timeliness of its reporting. • Reports, which are less positive than the oral feedback, disappoint NHS staff and managers. 	<u>NHS managers:</u> There are no further mechanisms to share best practice identified during the inspections. <u>HIW:</u> Inspection results inform decisions of independent hospital users.
Action plans and Follow-up <ul style="list-style-type: none"> • In the recent past, neither the Welsh government, nor HIW have systematically followed-up how far action plans were implemented by NHS organisations. • HIW inspection manager has rigorously checked and followed-up any breaches in the independent sector. 	<u>NHS managers:</u> Improvement plans have not always been published together with the inspection reports on HIW website. This can create a wrong perception.
Enforcement <ul style="list-style-type: none"> • HIW uses informal and formal mechanisms to act upon non-compliance, though HIW has (on its own) only regulatory powers over the independent sector. 	
Impact <ul style="list-style-type: none"> • HIW inspections have been effective in some areas and with some organisations. This particularly concerns improvements of the physical infrastructure of hospitals, staffing levels and, to some extent, clinical care / behaviour. • HIW inspections helped to change priorities and reallocate funds to implement the recommended actions. 	<u>NHS managers:</u> HIW inspection findings give additional weight and leverage to convince decision makers or certain professional groups.

The next chapter will reflect on the above findings, examine the mechanisms which contribute to regulatory effectiveness and discuss them in light of previous studies.

Part III. Reflections on the research findings

The third part of the thesis critically reviews the findings from the interviews and document review, which were presented in part II. Chapter six mainly discusses the two research questions: (i) which elements and mechanisms of the inspection regimes have shown to be effective or not in which setting and (ii) what modifications to the inspection regimes are likely to improve their effectiveness. Chapter seven summarises the major conclusions and recommendations and thus completes the thesis.

6 Effective elements and mechanisms of HIW's inspection regimes

The current chapter discusses the findings of this thesis and compares them with other studies. Following a theory-driven realist evaluation approach, the aim of this thesis is to examine under which circumstances particular elements of HIW inspection regimes are effective or not. By comparing the identified patterns with findings from evaluations of hospital inspections in similar and dissimilar settings, particularly England, the discussion aims to test and refine the initial conjectures and identified configurations. Furthermore, the chapter contemplates possible improvements to the inspection regime, either proposed by the participants or the author herself, and reviews their potential success.

The discussion generally follows the thematic framework, but at times goes beyond the boundaries of the three stages of the inspection regime, i.e. pre-inspection, on-site inspection and post-inspection, in order to establish effective mechanisms across the regime.

6.1 Pre-inspection

The discussion starts with the four elements within HIW's inspection regimes, which are supposed to direct the healthcare organisations, establish a common understanding of the expected performance and inform HIW's decisions on which issues and sites to inspect. These comprise (i) healthcare standards, (ii) registration, (iii) self-assessments and (iv) selection of inspection sites.

6.1.1 Standards

The interviews suggest that noncompliance of NHS hospitals in Wales neither results from unfamiliarity with nor unattainability of the healthcare standards. Due to resource limitations and work pressure, NHS managers tend to interpret standards less ambitiously than their counterparts in the independent sector. The contextual factors, limited funding and high work load, inhibit the potential of HIW's inspections to drive improvement in the NHS. The involvement in the standard development process, specific indicators and guidance on how to meet the standards facilitated understanding and acceptance amongst independent hospital managers. To foster ownership, the standard-setting process needs to be transparent and 'genuinely consultative', which concurs with Walshe (2003, p. 19) and Hilarion et al. 2009. This entails that alternative proposals are discussed, and rejections explained. In this respect, the previous development of independent sector standards in Wales seems more successful than the review of health and care standards in 2014/15.

Regular reviews can ensure, as many participants and also Dixon and colleagues (2012, p. 13) argued, that the standards 'remain up to date'. However, the regular reviews of the generic healthcare standards in Wales seem not so much triggered by a 'use-by-date', but a change in the fashion of how to formulate standards. The generic standards in Wales possess a high face-validity, but they do not stem from clinical evidence, which according to Shaw (2003b) is not unusual for standards in statutory inspections. The vague formulations require proficiency on both sides, i.e. operationalisation by the hospitals and professional judgement by experienced reviewers. The flexibility and leeway for reasonable judgement seem to work effectively in independent hospital inspections.

The use of the term outcomes for the non-quantifiable healthcare standards in Wales (NHS Wales, 2015b) is, as Malley and colleagues (2014, p. 188) also noted for England, 'non-conventional', but in line with the shift from conformance towards performance improvement (Flynn, 2012, p. 168). The initial enthusiasm for outcome-based standards, 'the elusive aspiration of all inspectorates' (Day & Klein, 2004, p. 47), has substantially diminished due to the conceptual and practical difficulties (Gray 2001). It is therefore not surprising that the associated criteria, which the consultation process in Wales defined for the 'health and care standards', still leave room for interpretation.

Explicit, specific, quantifiable outcome-oriented indicators, which several healthcare managers advocated for, potentially make inspectors' judgments more consistent and reliable (Tuijn et al., 2011) and thus acceptable for hospital managers. Yet, they may not necessarily serve the purpose (Braithwaite & Braithwaite, 1995). Moreover, specifying standards and criteria for each healthcare service can be a lengthy undertaking, which according to Boyne (2003) may quickly turn into conflict.

The recognition by one senior NHS manager that the standards drive mediocrity within her organisation corresponds with Walshe and Boyd's (2007, p.29) attribution of minimal standards 'as a limit on rather than a stimulus for improvement'. Judging from the interviews and documentary evidence, this effect seems more likely to occur in large, complex NHS organisations in Wales than in small, specialised hospitals or wards with dedicated managers and clinicians. In this respect, the large size and thus the manageability of healthcare organisations seem to influence the effectiveness of HIW's inspection regimes beside the above-mentioned amount of funding and work load. Butterfield and colleagues (2012) argue that published reports of external peer reviews make it more difficult to hide mediocre healthcare, yet, this implies that organisations are regularly peer-reviewed and reports published and read.

6.1.2 Registration

Although close cooperation between HIW and applicants prior to registration is more resource-intensive for HIW than a mere registration-inspection, the investment in time and efforts can be effective and seems worthwhile, as the example presented earlier (viz. 5.1.2 Registration) showed. The better understanding of HIW's expectations may have contributed to the positive inspection results after the registration. The mutual respect which evolved through the intensive cooperation apparently enforced a positive attitude towards inspections amongst the hospital managers. This finding corresponds with Walshe and Boyd's (2007, p. 21) description of positive relationships between the regulator and regulated organisations, which is based on a 'shared sense of purpose, and mutual recognition of each other's expertise and contribution'. Such a relationship has the potential to promote improvement (Walshe, 1999). The small number of acute independent hospitals in Wales as a contextual factor facilitates the development of relationships and better insight.

HIW's failure to conduct annual inspections in the years after the registration, however, undermined the confidence of the hospital managers in HIW's inspection regime. The decision not to inspect a hospital with excellent performance data on an annual basis would have been a legitimate reason regarding HIW's limited resources and its proportionate inspection approach, yet the inspectorate failed to communicate the reasons to the hospital managers.

The suggestion to expand the registration and licensing to NHS organisations, as currently practised in England, appears at first glance legitimate, but it is questionable whether this would lead to more regulatory effectiveness. Given the NHS's predominant role in Wales, such a decision would be highly political and symbolic. It is hard to imagine that, in case of a serious breach of standards, an NHS organisation would take HIW's threat to revoke the registration seriously. The threat itself, however, would be a serious disgrace, which any organisation would be advised to avoid.

The recent introduction of HIW relationship managers and lead review managers for each Local Health Board aimed to facilitate the relationship with NHS bodies and thus may have the potential to achieve a similarly positive effect in the NHS as the independent sector. However, the contextual factors, such as larger size of health boards, many hospitals, limited financial resources and high work load, are much less conducive in the NHS.

6.1.3 Self-assessments

The internal information, which healthcare managers have access to, puts them in a much better position than HIW to make an accurate assessment about a hospital ward. The large size of many Local Health Boards (LHBs), however, impedes monitoring and requires corporate quality assurance and governance mechanisms. This finding coincides with Gilad's (2010) conclusion that organisational complexity inhibits compliance and learning from failures.

The attempt to embed the standards in the healthcare organisations through self-assessments (Thomas 2013) has only partly been successful in Wales. The enthusiastic expectation that this 'radical new' approach would enable HIW to target resources 'on areas where they are most needed' (Jewell & Wilkinson 2008, p.309) ignored the contextual factors, particularly the resources required for HIW's reviewing and testing. In the attempt to shift the cost of assessing compliance to the LHBs, the approach added regulatory burden without adding value, since HIW could not sustain the cost of reviewing and validating the self-assessments.

By their nature, self-assessments are judgements, which entail a certain leeway. The examples of Mid Staffordshire, Maidstone and Tunbridge Wells show the danger of inaccurate, insufficiently tested self-assessments (Bevan, 2008; Francis, 2013). Given the apparent deficiencies with the self-assessment, it is unclear on which basis the Older People's Commissioner for Wales concluded that HIW had 'pre-empted the criticisms made in the Francis report' (Rochira, 2013). The self-assessments cannot solve the underlying problem of the principal-agent-relationship between the government and NHS bodies.

Continuing the self-assessment process despite the lack of considerable feedback requires a mature organisation that recognises the benefit of the approach. According to the participants, not all healthcare organisations in Wales are sufficiently committed, open to identify issues and willing to learn and improve. In some NHS organisations, self-assessments seem to have degraded to a paperwork exercise with limited value. The incoherence in self-assessment mechanisms, content and format across NHS bodies as well as the few publications of self-assessments are not conducive for benchmarking and shared learning.

The statement of a senior HIW manager that each method and tool have their merits, but become increasingly obsolete over time, seems to hold true concerning self-assessments in Wales.

6.1.4 Selection of inspection sites and pre-inspection information

Despite HIW's (2012b; 2014a) claim of a risk-based approach, its previous hospital inspections were not induced by a thorough intelligence-based risk assessment. Neither the very few hospital inspections in 2013/14, which reflected HIW's organisational difficulties, nor the much higher volume in 2014/15, which was motivated by HIW's desire to show presence and restore public confidence, mirrored lower or higher risk levels of hospital care.

HIW's former practice to predominantly inspect hospital sites randomly and without announcement presumably depicted NHS care in Wales realistically and prevented staging.

The interviews and the literature review (Adil, 2008; Bevan & Cornwell, 2006; Walshe & Phipps, 2013) suggest certain prerequisites for effective risk-based inspections, including

- (i) Access to relevant, material, reliable and timely information and data, which ideally are consistent and comparable to ensure 'predictive validity' (Walshe & Phipps, 2013),
- (ii) Capability to analyse and interpret the data,
- (iii) Capacity to act promptly.

While the exchange of intelligence across the review bodies in Wales has reportedly improved (Thomas 2013; Rochira 2013), access to essential ward-specific data would help HIW to more effectively spot and select poorly performing wards as inspection sites. Variations inside one hospital are not restricted to Wales (Berwick et al., 2013). This corresponds with Dixon and colleagues' (2012, p. 13) statement that 'very few providers are consistently either substandard or excellent across all their services'. The difficulty to determine a set of crucial indicators for risk rating is not HIW-specific (Day & Klein, 2004; Griffiths et al., 2016).

The interviews and document review clearly showed that HIW did not always utilise intelligence from other stakeholders and take appropriate action (Anon 2013; Community Health Council 2013; Thomas 2013; Andrews & Butler 2014). The criticism mainly relates to the period between 2012 and 2013, when HIW's ability to analyse and promptly act upon identified risks was undermined by limited funds and staff. While, since then, HIW's capability has slightly improved through the recruitment of data specialists, the task to choose the right set of indicators from a vast amount of available data is rather Sisyphean. Likewise, HIW's flexibility and thus its ability to act promptly have increased

through the expanded pool of peer reviewers. The latter, however, need lead time to arrange for their secondment, an inherent downside of the peer review approach.

A weakness in applying a data-driven approach is the dependence on retrospective and partly self-reported data, which are, as the peer reviewer's example of 100% compliance with hand-hygiene procedures demonstrates, not always reliable. Arguably, good performance data do not automatically signify good healthcare. If an inspecting body only relied on self-reported data (Mears, 2014), hospitals may feel tempted not to report incidents (European Partnership for Supervisory Organisations in Health Services and Social Care, 2012) or to manipulate data reports. Yet, no evidence has been found during the interviews that hospital managers in Wales deliberately manipulate data to circumvent inspections.

This study found no evidence, either, that prior knowledge of positive performance data had incorrectly shaped the reviewers' judgement and led to less vigilant inspections. Though, HIW managers and reviewers expressed their awareness that prior knowledge might frame the reviewers' expectations. HIW's failure to notice a problem during an inspection, which one participant mentioned, cannot be explained by a positive bias, since the respective LHB was under enhanced monitoring and the suboptimal performance data were openly displayed.

The example of the Trusted-to-care spot-check, which identified severe problems despite 'wonderful data' either signposts a case of false data or an unrepresentative 'bad day'. Whatever the case was, the external inspection alerted the hospital (and the public) about the issues and required counteraction. The problems on that ward on that day would have remained unidentified, had the spot-check omitted the hospital site with 'wonderful' data. This exemplifies the legitimacy of deviating from a targeted, purely data-driven inspection approach and may prevent 'game playing' (European Partnership for Supervisory Organisations in Health Services and Social Care, 2012, p. 36). Conversely, a purely random selection of inspection sites, which might generate a more representative and positive image of Welsh hospitals, would potentially prevent HIW from detecting poor wards with poor performance data. This can neither be in the public's interest nor, in the long run, in the LHB's interest. Stratified sampling would require that hospitals can be accurately assessed and clustered prior to the inspection (European Partnership for Supervisory Organisations in Health Services and Social Care, 2012).

The findings also demonstrate that large intervals between inspections combined with the pretence of a risk-based approach can create the false impression and thus false assurance that hospital services are not inspected, because they are safe. This jeopardises HIW's role in providing assurance. Contextual factors, such as the large size

of healthcare organisations and aggregated data make it more difficult for HIW to identify poor performing parts of the organisation, and thus for the inspection regimes to become more effective.

6.2 On-site inspection

The discussion continues with the five aspects and components which are relevant at the time when the hospital is inspected. This relates to the (i) frequency, duration and depth, (ii) inspection mode (iii) methods and tools as well as the (iv) inspection team. These factors are instrumental in detecting whether a hospital is compliant or not with the respective regulations and standards.

6.2.1 Themes and topics

The thematically more focused inspections in independent hospitals in 2014 and the contrary development towards a wider thematic scope in NHS inspections at the same time can be interpreted as an approximation between the independent and NHS inspection regimes, which Walshe (2008) noticed earlier in England. To the researcher, the differentiation between the two inspection regimes does not seem plausible with regard to HIW's (2015a) role as 'independent inspectorate and regulator of all health care in Wales'. A unified inspection regime would facilitate a comparison of inspection results amongst independent and NHS hospitals.

The changes in HIW's hospital inspections, which many participants noticed during 2014 and 2015, reflect the findings of the Andrews and Butler (2014) report and the subsequent Trusted-to-care spot-checks (NHS Wales & Welsh Government, 2014a) in 2014. This indicates HIW's responsiveness to changes in the contextual conditions as well as its regained operational capability. The envisaged development of specific modules and their integration in the inspection regime can increase HIW's flexibility. The regular updating will require external expertise and sufficient funding. In the past, the Welsh government had strongly influenced HIW's inspection themes. HIW's affiliation with the Welsh government undermines HIW's claim to be an independent inspectorate and regulator, yet, a more active engagement by the government could be instrumental in enforcing corrective actions and/or improving healthcare.

Although this study did not find any hard evidence, it can be assumed that healthcare managers are more willing to act upon HIW's recommendations, when they consider the inspection topics important and not 'whims'. The variety of opinions amongst the participants as to which topics and aspects HIW inspections should focus on, reflects the complexity of healthcare and the difficulty that any inspectorate faces when designing inspection regimes. They relate to the different theories of inspections (Davis & Martin,

2008) and models of improvement (Boyne, 2003). Arguably, reviews and inspections should encompass both, analysing the appropriateness of the hospital systems and governance arrangements as well as testing practical healthcare delivery at frontline level. Also the suggestion to review patient pathways seems very topical due to the complex challenges of cutting across specialties and organisations (Butterfield et al., 2012).

HIW's thematic reviews, which go beyond the level of individual hospital inspections, can inform the government and other stakeholders about current trends and common issues in Wales. Marks (2014) called for a balance between individual inspections and thematic reviews given the considerable impact of the latter. HIW's (2015n) thematic DECI report draws conclusions from the individual DECI reports and thus provides added value. It would be worthwhile investigating how thematic reports are being used and can be further improved to drive learning and improvement across different healthcare organisations.

6.2.2 Frequency, timing and duration

Given the imbalance between HIW's inspection volume and the potential inspection sites, HIW's ability to provide quality assurance to the local health boards (LHBs) and the public is restricted. The low frequency of inspections between 2012 and 2013 undermined HIW's credibility severely. Not surprisingly, LHBs subsequently established corporate governance systems, which include internal inspections. This shift can be seen as a form of enforced self-regulation (Hood, James, & Scott, 2000), though it occurred, alerted by the prominent failings in UK healthcare, as a voluntary reaction, unlike the self-assessments, which were imposed by the government. NHS organisations began to understand that they cannot rely on external inspections only, although it is convenient to blame the regulator for failures, as in case of CQC (Torjesen, 2012).

Restricted by its resources and conscious of the interdependency between the quantity or frequency of inspections on one side and the length or intensity of each inspection on the other, HIW has apparently experimented to find the optimal balance. HIW's practice in 2014/15 to inspect only one ward within a hospital might have been instrumental in identifying patterns across NHS hospitals in Wales, but it failed to identify further-reaching conclusions and common themes across the wards within the same hospital. The increase in inspection sites per hospital in 2015/16, which seems to be inspired by the Trusted-to-care spot-checks and which several participants advocated for, paid tribute to the variation of care within a hospital and thus facilitates comparison. The downside is a reduction in the number of hospital inspections and, admittedly, in the depth of each ward-inspection. Nevertheless, the findings do not suggest that the shorter duration per ward generated less reliable inspection results. HIW should consider

occasional out-of-hour hospital visits with regard to the benefit they showed in HIW's mental health inspections.

The quick succession of HIW inspections, which many participants complained about in 2014, and their adverse impacts are not an uncommon phenomenon. Walshe (1999) noticed already in 1999 an inspection fatigue resulting from many inspections in short sequences. The complaints about being over-inspected seem to predominantly derive from uncoordinated inspections amongst the various review bodies. This included in 2014/15 the Community Health Councils' (2014) Hospital Patient Environment visits in 420 inspected areas within eighteen major acute hospitals and sixteen community hospitals and the Welsh government's Trusted-to-care spot-checks of 70 wards in 20 district hospitals (NHS Wales & Welsh Government, 2014a).

The figures that interviewees presented as evidence for their complaints were not always plausible. The claim by one senior NHS participant about fourteen DECIIs and Trusted-to-care spot-checks within two months does not correspond with the published figures, unless the participant included in her calculation the LHB's own internal inspections, which her hastily added half-sentence suggests: 'because we also run our own [...] internal inspection function.'

There is clearly a need for the various review bodies to coordinate, which concurs with Marks (2014). Joint or coordinated inspections can reduce cost and the burden for healthcare providers (Hampton, 2005), i.e. negative impacts of regulatory practice.

6.2.3 Unannounced and announced inspections

The appreciation for unannounced inspections amongst most of hospital managers seemed genuine, particularly since the participants express their preference voluntarily. It is plausible that senior managers of large LHBs appreciate external inspection findings as instrumental in identifying problems, which they struggle to spot due to the hierarchical gap and physical distance.

Announced inspections are very likely to induce preparation and thus potentially give, as some participants warned, false assurance to the senior managers. The suspicion that announcements lead to preparation is supported by the experiences which peer reviewers and hospital managers shared during the interviews. The instanced examples are similar to those that Walshe and colleagues (2014) reported for CQC's announced pilot inspections. The accounts from Wales highlight that the distinction between unannounced and announced inspections can be ambiguous, particularly, when a visit is foreseeable.

The statement of one manager that her hospital did not change anything due to the unknown inspection area and date implies that the organisation would otherwise have taken precautionary measures. This indirectly confirms the potential of inspections, that are announced or likely to happen, to drive rapid improvements, if time, resources and managerial/professional competencies suffice. A pre-emptive or catalytic effect (Day & Klein, 2004) can potentially arise from the fear that an unannounced inspection could arrive at any moment, discover shortcomings and make them public. HIW's increased use of public and social media can help to create an impression of inspection frequency. A pre-emptive effect is unlikely to occur, when an inspectorate hardly conducts any inspections and/or hospital managers consider their hospital unlikely to be targeted, as in case of HIW in 2012-2014. A more frequent, comprehensive regime of unannounced inspections would enable HIW (2016e, p. 11) to go beyond capturing 'a snapshot'. More frequent and intensive inspections, however, add to the regulatory burden and inspection fatigue (Walshe, 1999), i.e. negative side-effects.

External inspections are, no matter how unobtrusively conducted, disruptive. Unannounced inspections disturb the care process more than announced inspections, since hospital managers cannot allocate sufficient staff to the inspected ward in advance to compensate for the staff time that HIW inspections tie up. The anxiety of being under scrutiny, which most participants reported about, is a common phenomenon that is not confined to unannounced inspections. It also occurred during CQC's announced inspections (Walshe et al. 2014). In contrast to unannounced inspections, the prior knowledge of an announced inspection can trigger distress amongst staff and had, according to one interviewee, undermined operational activity days before HIW's visit.

As the interviews revealed, the level of anxiety depends on various contextual factors, such as the personality and previous experience of the hospital staff, the conduct of the inspection team and specific circumstances, such as work pressure. Here, many healthcare managers seem to play an intermediary role in providing moral support to frontline staff.

HIW's fear of information leaks has apparently hampered coordinated scheduling amongst review bodies and thus potentially increased the distress and regulatory burden. It cannot be determined whether the participant's experience of more 'intimidating' NHS hospital inspections is representative. It is plausible that an inspection of a smaller and better resourced (independent) hospital might detect less negative findings and therefore cause less distress amongst the inspected staff.

Regarding its capacity and existing inspection schedule, it is understandable that HIW does not accept all invitations. When it does, hospital managers appreciate HIW's

findings and recommendations. The example of an invited HIW review, which started in October 2011 and comprised seven people and inspections of nine different hospital areas, indicates the implications for HIW's (2012a) resources. The time-span of approximately 18 months between the LHB's request of the review and the publication of HIW's report illustrates the practical limitations.

6.2.4 Inspection methods and tools

HIW's approach to combine various methods and thereby use all the human senses rather than exclusively relying on pre-inspection data analysis has proven right with regard to the criticism that CQC had previously faced (Hawkes, 2011; Strategy Group Department of Health, 2012). The confidence in HIW's inspection methods, which healthcare managers expressed in general, reflects their agreement with this approach and speaks for its potential effectiveness.

The criticism that HIW inspections concentrate on process-related data and information rather than on quantifiable outcomes is understandable regarding the prominent failings in recent history, which were associated with higher mortality rates. Internal processes are indeed, as Boyne (2003, p. 222) explained 'only rough proxies' for service improvement. In the absence of a more appropriate method and based on the observation that hospitals with 'better processes of care have better outcomes' (Brook, McGlynn, & Shekelle, 2000, p. 291), processes are predominantly measured to assess healthcare quality.

A mixed assessment approach could help to relate the weaknesses in the process of healthcare (i.e. not only nursing care) and inputs with the outputs and outcomes. Though, HIW's (2015m, 2015o) inspections started paying more attention to staffing levels, which is a critical input factor for patient safety (Berwick et al., 2013; Francis, 2013; Veillard et al., 2004). It remains unclear why HIW inspections have not gathered and reviewed (more) outcome data for the inspected wards, as several participants criticised. This might relate to (i) the difficulty to identify a set of meaningful outcome indicators or (ii) the lack of analytical skills of the reviewers on site. Also Walshe and colleagues (2014) noted difficulties CQC reviewers had to interpret quantitative data. Here, HIW's data analysis team could support the reviewers in identifying which ward-specific data to collect and how to interpret.

HIW's claimed patient-focus has manifested itself through the assignment of lay reviewers and patient interviews. Given the importance of appropriate interview techniques for gathering authentic information, HIW's training of lay reviewers seems a good investment. However, the patients' perspective of quality healthcare typically

concentrates on their perception of care and wellbeing (Jenkinson, Coulter, & Bruster, 2002) rather than on medical treatment and clinical effectiveness. Since interviews with inpatients may be biased (Bowling, 2005), statements should ideally be triangulated. Healthcare managers doubted the claims made by HIW's peer reviewers that patient statements and single observations were always triangulated. More transparency can help to build or restore trust in the inspection methods. Where available, more objective assessment methods, such as measuring the temperature of patients' food, should be used, before generalising singular statements of patient experience.

If the patient survey in 2014/15, as the thematic DECI report states, covered 46 wards, then approximately seven questionnaires were on average returned per ward (Healthcare Inspectorate Wales, 2015n). This figure matches with a DECI at Powys Teaching Health Board where seven out of 20 distributed questionnaires were returned (Healthcare Inspectorate Wales, 2015l). The low response rate might result from the self-administration, which conversely can 'encourage reporting of some sensitive information' (Bowling, 2005, p. 288). Such a survey is hardly representative of the healthcare on a particular ward throughout the year, yet, the analysis of all ward surveys may help to identify issues and patterns across NHS hospitals in Wales.

The evidence from the interviews and HIW reports (see example below) clearly shows that HIW inspections received information from interviewed staff, which otherwise would be very difficult to obtain.

'We held conversations with ward staff and were informed that there had been a number of occasions when the ward had not been able to obtain a sufficient stock of pillows to ensure patients' comfort.'
(Healthcare Inspectorate Wales, 2015j, p. 11)

It is plausible that frontline staff may not have the full overview on the organisation, especially when they are young and new or just returned from a long absence. Concerns that junior staff are generally more negative in their views were also raised over CQC inspections (Walshe et al., 2014). According to Walshe and colleagues many hospitals in England therefore prepared their staff for a CQC visit. Senior NHS managers in Wales try to 'prepare' their staff through internal inspections, which, however, adds to the perceived burden of inspections. Negative views may not necessarily result from a lack of knowledge or experience, but possibly from stress, overwork and organisational culture. Ideally, the healthcare organisation should have internal mechanisms in place to deal constructively with criticism. External inspections can and have activated staff to come forward with criticism. While leading questions by HIW reviewers might promote the information transfer, they undermine the credibility of inspections amongst hospital managers.

Some middle-level NHS managers have expressed a positive attitude towards inspections by allegedly encouraging their staff to speak out during the inspections, thereby hoping to influence the LHB's top management decisions. This shows that managers aspire to play a more active role during HIW inspections and corresponds with Day and Klein's (2004, p. 3) finding that inspections can give extra leverage to those who are 'seeking to change organisational practice and attitudes.'

Despite HIW's claims to conduct discussions with senior managers, the latter used to become involved only after the hospital inspection: either during the debriefing or when HIW's draft report arrived. This practice differed from (i) HIW's independent hospital inspections where discussions with senior managers form part of the inspection methodology and (ii) CQC inspections, which interview executive managers, clinical directors, matrons and service managers (Walshe et al. 2014). HIW's previous reluctance or avoidance to meet healthcare managers during the inspection, which NHS participants perceived as deliberate, can be attributed to HIW's attempt to minimise the risk of capture. However, senior healthcare managers can potentially add information that contextualises the inspection findings and prevents misinterpretation. HIW's (2015o) later inspections in 2015 included 'Discussions with senior management within the directorate' and 'consideration of quality improvement processes'. Also the interview during an inspection in 2015, which a senior NHS manager reported about in this research (viz. chapter 5.3.3 Inspection methods and tools, page 85), signifies a change in HIW's practice.

Though HIW aims to minimise the adverse effects during the inspection, interviews with hospital staff will unavoidably tie up human resources, as discussed above. The lack of coherence amongst review bodies, in how hospitals have to present their documents and evidence, adds to what various authors (Dixon et al., 2012; Hampton, 2005) describe as regulatory burden. A more coherent approach would be preferable.

While there is no doubt that reviewers need to have some tools, which ensure methodological consistency, it seems difficult to find the right balance between structure and room for professional judgement. Though, even highly structured evaluation tools do not seem to eliminate the variation in the interpretations of criteria and evidence (Øvretveit, 2005; Tuijn et al., 2011). While many interviewees perceived long, structured questionnaires as tedious, structured interview and inspection tools help reviewers to detect and address relevant aspects (Tuijn et al., 2011). The tendency for inbuilt redundancy across the various tools is not confined to Wales. In the piloted CQC inspections in 2014, the attempt to capture the particularities of the inspected areas by

expanding the prompt cards-like 'key lines of enquiry' led to duplication (Walshe et al., 2014, p. 37).

Finding the right balance also applies to the renewal of tools: while some reviewers advocated for more frequent reviews, introducing new tools and methods requires reviewers to learn and adapt. Both, developing tools and (re)training reviewers, costs time and money.

In the past, inspections relied on long questionnaires and checklists. The new trend seems to be prompt cards, as CQC's pilot inspections, the Trusted-to-care spot-checks and the internal visits of one LHB (Cwm Taf University Health Board, 2014) suggest. Also, HIW's assessment tools for independent hospitals are like prompt cards. They are structured by headings with much space for notes. However, due to their complexity, they contain many sheets. The prompt card approach requires an experienced professional with the necessary specialist background, who is able to ask the right questions, interpret the answers and ask more profoundly when necessary. The example of the Trusted-to-care spot-checks shows that reviewers can master the loosely structured tools successfully. Newly recruited peer reviewers may find this difficult and reviewers without a healthcare background are likely to fail. Moreover, prompt cards require additional time and a good memory to write up the notes after the interview.

While prompt cards allow for more flexibility, structured interviews with a standardised tool suggest a higher consistency. As several participants emphasised, overreliance on structured tools can lead to incorrect conclusions. In CQC's pilot programme, which employed many specialists, inspectors emphasised the importance of allowing 'space for inspectors to use their professional judgement' (Walshe et al., 2014, p. 38). Prompt cards seem to be a good compromise between structure and flexibility (Argy & Johnson, 2003).

The degree of transparency has varied across HIW's inspection regimes and over time. The fact, that some NHS organisations possess the DECI tools, (while others presumably not) creates inequality amongst the healthcare organisations and may distort the inspection results.

It would be interesting to investigate in future studies

- How far the prior knowledge of tools affects the inspection results and the effectiveness of the inspection regime,
- Whether hospital managers and staff concentrate on the areas captured by the tool and neglect the others or

- Whether poorly-performing hospitals are too weak to take advantage of the prior knowledge of the tool.

6.2.5 Inspection team

The opinion that inspection teams should comprise a mix of relevant competencies, which HIW and healthcare managers expressed, is widespread (Butterfield et al., 2012; Walshe, 2003; Walshe & Phipps, 2013). Although most participants focused on the importance of specific clinical expertise within the inspection team, the interviews also highlighted other essential competencies, including leadership and communication skills as well as familiarity with the healthcare standards in Wales. The multitude of requirements calls for a multidisciplinary team with complementary skills. It seems that a team size, which ranges between three and five members per inspection site, is generally accepted by hospital managers and sufficient for HIW's regular inspection regimes.

In contrast, CQC's inspection teams in 2013/14 'averaged approximately 30 members for a single site acute hospital NHS' (Walshe et al., 2014, p. 26). Unsurprisingly, the evaluators noticed difficulties resulting from large teams and questioned sustainability (Walshe et al. 2014). Large inspection teams are not feasible in Wales with regard to the government's and HIW's financial limitations, the disruptions and likely resistance.

The interviews with peer reviewers and healthcare managers suggest that a clinical background of HIW's review managers adds to the credibility of HIW's inspection regimes. Moreover, clinical proficiency reduces the review managers' dependency on peer reviewers and positively affects their position in the team. Nevertheless, the positive experiences that peer reviewers described with HIW review managers prove that also non-clinicians can successfully act as inspection leader as long as they have other relevant skills. The problem that one peer reviewer experienced with an overstrained, inexperienced HIW inspector apparently relates to HIW's organisational problems during 2012-2014. This and the reported reluctance of some review managers to exert leadership may stem from an unclear distinction of tasks and/or the perceived natural authority of (clinical) peer reviewers with a strong personality. Also Walshe et al. (2014, p. 31) found 'some areas of confusion regarding the breadth of the role of external inspectors' in CQC pilot inspections. A clear delineation of responsibilities may help to overcome some of the ambiguity.

The way reviewers act and interact with people most likely influences the effectiveness of inspections:

- From the interviews, it can be deduced that a lax reviewer, who superficially inspects, neither commands respect nor prompts changes in healthcare organisations,
- Neither are healthcare managers inclined to act upon findings and recommendations, which come from a reviewer who acts with unreasonable and confrontational rigidity.

The interaction between the independent managers and HIW's inspection manager seemed to have developed into a relationship of mutual respect, which has been conducive for HIW inspections and did not show signs of fraternisation or capture.

The variable quality of inspections, which NHS participants related to varying levels of expertise of particular reviewers, is not dissimilar from the 'varying levels of experience within and across inspection teams', which Walshe and colleagues (2014, p. 27) observed in CQC inspections. It is naturally more difficult to compose and manage a suitable team for a new and large inspection regime than for a small and established inspection regime, such as HIW independent hospital inspections. It is plausible that the discontinuity in HIW staff during 2012-2014 and the subsequent recruitment of new peer reviewers had contributed to varying quality, which NHS participants noted in HIW inspections.

The decision to assign peer reviewers on a temporary, contractual basis and not to employ clinical specialists on a permanent basis was not only economically-driven. This arrangement has increased HIW's flexibility to respond to specific or changing requirements. Permanently employed clinicians will find it difficult to maintain and update their clinical skills. The criticism concerning out-dated peer reviewers' expertise points to the dilemma, HIW is confronted with:

- Peer reviewers who work as clinicians tend to be familiar with the latest clinical developments but are time-wise less flexible.
- Retired peer reviewers are time-wise more flexible, but out of practice.

The rotation scheme, which one NHS participant proposed instead, entails potential downsides, which are related to the temporary employment, training needs and high staff turnover.

Despite some disappointment with particular reviewers, the interviewed healthcare managers generally welcomed HIW's approach. Documentary evidence confirms that some NHS organisations in Wales actively encourage their nurses to become peer reviewers in order to prepare for hospital inspections and address problems prior to an external inspection (Cardiff and Vale University Health Board, 2014). Fortunately, HIW

had never abandoned the original approach, while CQC's earlier decision to replace the peer reviewers by generic staff had been blamed for the failure to detect severe shortcomings at the inspected hospitals.

It is plausible that the interviewed healthcare managers accept findings more readily when they know that the reviewers are experienced specialists. Apart from the peer reviewers' clinical expertise, HIW inspections benefit from inside knowledge of hospital systems and data manipulation. Also, Walshe and colleagues (2014, p. 28) recommended in 2013/14 'that the specific composition of the inspection team (particularly the representation of clinical specialties) should be driven by any concerns identified in preliminary data gathering or routine monitoring.'

The great popularity that the Cancer-peer-review programme enjoyed amongst the participants signposts a potential for expanding similar programmes across Wales and beyond (Butterfield et al., 2012; Klazinga, 2000). The double role which peer reviewers play and the change of attitudes, that peer reviewers described, can help to generate sustainable behavioural and organisational changes. This seems particularly probable when peer reviews become widespread and include medical and other professionals. The absence of medical professionals within the review teams allows physicians to distance themselves from HIW's hospital inspections, as several participants noticed and the failure to recruit medical professionals for this study demonstrates. Interestingly, the organisers of the Trusted-to-care spot-checks in 2014 failed to recruit medics to complement their teams.

HIW's practice of engaging lay reviewers is a relatively new concept. Many participants appreciated the potential for lay reviewers to establish a rapport with patients and thus collect authentic information. There is, however, no proof that other team members, such as non-clinical review managers, are not equally capable of performing this role. Lay reviewers do not per se have the necessary communication skills. The lay reviewer's ignorance, which some interviewees valued as an advantage, may impede the inspection process, as does a dubious motivation behind becoming a lay reviewer. While review bodies such as HIW and CQC use previous service users in their mental health inspection schemes, it is unclear to what extent the profile of lay reviewers matches the thematic area of other inspections and whether this is essential. Though, it is plausible that lay reviewers with topical experience detect unacceptable practices by asking informed questions to patients and service providers.

It seems unlikely that the change in the lay reviewers' compensation will jeopardise the quality of inspections, as a conservative MP suggested by blaming HIW for 'downgrading the only role in the inspection teams dedicated to monitoring the patient experience'

(BBC, 2015). Intrinsically motivated lay reviewers are unlikely to be deterred by the new policy.

Team bonding reportedly facilitated the work and effectiveness of the Trusted-to-care spot-checks and HIW's independent hospital inspections. Large pools with many external reviewers and occasional meetings are hardly conducive for team building in NHS hospital inspections. Regular meetings and training sessions for external reviewers are, as the interviews revealed, important for the improvement of HIW's inspections. It is advisable that HIW continues and, if funds allow, intensifies its training schemes and meetings to periodically review its inspections regimes. Induction and training potentially increase consistency across inspections. Due to the large pool of external peer reviewers, fixed teams do not seem an option for HIW's regular NHS inspections. Nevertheless, HIW may consider special thematic meetings with a core team of external reviewers to further elaborate certain modules and elements of existing regimes.

To avoid misinterpretations, HIW should ensure that peer reviewers who are recruited from outside Wales are sufficiently briefed and knowledgeable about the healthcare standards.

6.3 Post-inspection process

The discussion continues with the five aspects and activities within the inspection process, which take place after the hospital has been inspected. This relates to the (i) immediate feedback, (ii) inspection reports and their publication, (iii) action plans, (iv) follow-up and (v) enforcement. These components are supposed to inform the relevant stakeholders about the degree of compliance with regulations and standards and, if necessary, enforce corrective actions.

6.3.1 Oral feedback and announcement of immediate actions

HIW's practice of conducting a debriefing on site corresponds with Dixon and colleagues' (2012, p. 7) recommendation that regulators should support providers by 'feeding back to staff the findings of inspections'.

The interviews revealed that independent managers proactively seek HIW's advice and act upon it. Informed advice reinforces the positive attitude towards HIW's inspections and, by implementing the recommendations, most likely improves healthcare. For this mechanism to be effective, it is essential that HIW's reviewers have the required and recognised professional expertise and, ideally, hospital managers appreciate HIW's findings and recommendations as 'free consultancy' (Walshe et al., 2014, p. 67). In the interviews, NHS participants typically perceived HIW inspections as a means of external quality control or assurance, rather than quality improvement.

The practice of explaining the rationale for a judgement, as one HIW interviewee emphasised, conforms with good practice to 'disclose the criteria' that inspectors 'use to form judgements' (Office of Public Services Reform, 2003, p. 34). The healthcare managers' complaints about insufficiently substantiated generalisations resemble some of the difficulties that Walshe and colleagues (2014, p. 47) describe 'concerning the categorisation/sorting, weighting/valuing, and synthesising of evidence' in CQC inspections. The preparatory meeting can be instrumental in verifying and consenting the statements amongst the team members. 'Corroboration meetings' were also considered an important mechanism in CQC's piloted inspections (Walshe et al., 2014, p. 41). Further investigation is needed to determine how to minimise the perceived variability in the quality of statements.

Hospital managers who consider negative findings and corrective actions as purely arbitrary or too ambitious will presumably only half-heartedly implement the imposed actions. If expectations are deemed unrealistically high, managers are unlikely to accept the criticism or desensitise. Lowering the expectations to the absolute minimum, however, will not drive improvement. Therefore, inspectors should have the discretion to contextualise and prioritise the findings. As the interviews established, the debriefing is not a one-way communication, but involves healthcare managers, who can help to clarify issues, correct inaccuracies and challenge views.

In emotive discussions, substantiating judgements with factual evidence seems as important as communication skills. These skills can be effectively rehearsed in role plays, as some of the newly trained peer reviewers evidenced.

Contrary to the perceptions of some peer reviewers, the overwhelming majority of interviewed NHS managers showed a keen interest in HIW's inspections and asserted to take the findings very seriously. This might relate to a self-selection bias in the recruitment of study participants. Similarly, Walshe and colleagues (2014, p. 59) noticed that hospital managers took the feedback at CQC debriefings 'very seriously'.

According to the participants, not all initial findings and recommendations found their way in the inspection report, and vice versa. This entails both deliberate decisions to drop minor or unsubstantiated findings as well as accidental omissions due to the delay in reporting and non-involvement of peer reviewers. Such discrepancies were also noticed for CQC inspections (Walshe et al., 2014)

While HIW understandably tries to be cautious about publishing over-enthusiastic judgements and findings, the inspectorate should avoid disappointment by forewarning the audience in the debriefings, as one participant suggested.

6.3.2 Immediate actions and management letters

The interviews and documentary evidence suggest that healthcare organisations take HIW's immediate assurance letters seriously, not least because of the potential embarrassment that is associated with their publication. In the absence of a rating, HIW and NHS managers seem to count immediate assurance letters as a (negative) benchmark. In its annual report to Betsi Cadwaladr University Health Board (BCUHB), HIW ranked the organisation last in an imaginary league table: 'Six Immediate assurance letters were issued to BCUHB following DECI inspections. This correlated to an assurance letter for every DECI that was undertaken – more than any other health board during 2014-15' (Healthcare Inspectorate Wales, 2015d, p. 10).

6.3.3 Reporting

The variety of opinions amongst HIW participants, concerning the target readership of its inspection reports, reflects the common 'problem of multiple potential audiences' (Day & Klein, 2004, p. 29). It is left to speculation about who really reads HIW's reports and how they can contribute to achieving HIW's regulatory objectives of assuring and improving healthcare quality. Whatever the pathways are, for the inspection reports to become effective, the respective audience needs to (i) become aware of and get access to the reported findings, (ii) read and understand them and (iii) take informed decisions and actions.

The previous delays in reporting have caused considerable damage to HIW's reputation. While this study did not find any evidence of consequential poor healthcare, participants admitted that the loss or delay of reports can impede improvement. This is likely to happen, when the inspected bodies do not act upon HIW's oral feedback but wait for the report and HIW's subsequent request for an improvement plan.

Not only were HIW's final reports published with a severe delay, but also the respective draft reports were submitted to the healthcare organisations well beyond HIW's target time. Reports that are written long after the inspection and possibly based on notes left by former reviewers are unlikely to accurately portray the situation of the inspected wards at the time of publication. Such reports, if not accompanied by updated action plans or at least a forewarning about the possibly outdated content, can misinform the reader. The lack of timely and accurate information hampers informed decision-making amongst the stakeholders, be it the hospital managers who were not present during HIW's post-inspection debriefing, service users or the government.

If reporting plays, as HIW claims, an important role in the effectiveness of inspections, it is incomprehensible that HIW's executive managers had left this problem unsolved for

such a long time. No single factor that HIW and other participants listed as a possible cause can explain the massive delays in reporting.

HIW's policy to submit its draft inspection reports to the inspected organisations for factual accuracy check is a good practice, which all interviewees appreciated and other review bodies exercise (European Partnership for Supervisory Organisations in Health Services and Social Care, 2012; Walshe et al., 2014). Occasional inaccuracies and misinterpretations in the draft report, which participants mentioned, signify a missed opportunity for clarification during the inspection process. The interviews with senior managers, which HIW has now embedded into its inspection methodology, and the involvement of peer reviewers in reporting-writing or checking are likely to improve the quality of draft and final reports.

This study did not attempt to determine public awareness of and reaction to HIW's activities. According to HIW reviewers, patients and potential hospital users contact HIW to receive information about certain (independent) hospitals. Negative publicity resulting from healthcare failures in England and Wales, the inquiry into HIW's effectiveness and HIW's increased physical presence since 2014 most likely raised HIW's profile and visibility over the last few years. The redesign of HIW's website in 2014 and 2016 as well as the use of social media show HIW's willingness to engage more with the public and its responsiveness to changing contextual conditions.

No information is available on whether the modifications in the reporting format, which were not consulted with the target groups, attracted more readers. What constitutes relevant content, appropriate language and style will most likely depends on the individual reader and the purpose of reading. Accommodating these potentially conflicting expectations in one report is a challenge for any review body (Day & Klein, 2004; Walshe et al., 2014).

The author of this study found DECI reports usually easy to understand for non-clinicians and thus the public. Summary chapters with sometimes three or more pages (Healthcare Inspectorate Wales, 2015g, 2016b, 2016c) positioned as the fourth chapter in DECI reports are, however, somewhat unusual. Potential readers may appreciate, as some participants suggested, a short overview with overall or detailed ratings. HIW's disinclination for a rating system is plausible given its resource limitations and the difficulty to establish a robust rating system, a challenge which also CHI (Day & Klein, 2004) and CCQ (Walshe et al., 2014) faced.

There is only scarce, international evidence available that supports the assumption (Ketelaar et al., 2011; Lavery et al., 2012; Shekelle et al., 2008) that public reporting

influences patients' choices. The effect seems to be rather selective and short-term. While there were some suggestions in this study that positive HIW inspection reports do inform potential clients of independent hospitals, it is not clear how far they influence decisions and attract new customers. A private customer might be motivated to actively seek information from the original source, i.e. HIW. The population in general is more likely to receive information through mass and social media.

Negative inspection results are more prevalent in the media than positive and thus more likely to influence people's perceptions. The population may not differentiate between wards or hospitals of a certain Local Health Board (LHB), though, quality and safety often differ significantly across wards. Since NHS patients in Wales are not generally 'provided with a range of choices' (Longley et al., 2012, p. 18), the 'selection pathway' (Berwick et al., 2003) can hardly be an effective mechanism in HIW's inspection regime. The interviews suggest that negative publicity does not necessarily deter NHS patients in Wales from using the hospital, but it can unsettle patients, when they come to the hospital for treatment. The predominant effect of negative inspection findings relates to the healthcare organisations directly. According to many interviewees, negative findings have triggered improvements at the inspected hospital and other healthcare organisations. Similarly, Lavery and colleagues (2012) and other studies established that high-profile investigations in England did not reduce patient numbers for more than six months, however, they prompted improvements inside the hospitals. A rating system which allows a direct comparison amongst hospitals could potentially increase competitiveness amongst LHBs. HIW's recent inspection regimes have not actively supported comparison and benchmarking, as healthcare managers noted in the interviews and one LHB during the public inquiry (Duerden & Hopkins, 2013). This may stem from the Welsh government's aversion to competition in public service provision (Bundred & Grace, 2008).

Apart from the inspection reports, HIW has not offered tools or mechanisms to support learning across LHBs. HIW's (2015n) thematic report on DECI and HIW's (2015b) annual reports to each LHB in 2015 seem first steps to facilitate comparison and learning. As these retrospective reports are issued only once a year, LHBs need to use their own real-time intelligence to identify problems and patterns. The Trusted-to-care spot-check reports were more pronounced, offering a separate section with positive findings called 'notable good practice' (NHS Wales & Welsh Government, 2014b, p. 20) and promising a 'Good Practice Directory' (NHS Wales & Welsh Government, 2014a, p. 21) to share the positive findings. Sharing and promoting information about good practice is a challenge that other review bodies have faced (Day & Klein, 2004; European Partnership

for Supervisory Organisations in Health Services and Social Care, 2012; Walshe et al., 2014).

The perceived focus of inspection reports on negative findings seems a universal phenomenon (Day & Klein, 2004; Mascini, 2013; Walshe et al., 2014). Conversely, inception reports that are perceived to be positive have a boosting effect on staff morale, as Walshe and colleagues (2014) noticed in England.

Healthcare organisations are unlikely to challenge positive findings. Since senior managers might not be aware of the situation on the ground, (unjustifiable) positive inspection results can give false assurance to managers and the public. Andrews and Butler (2014, p. 31) raised concerns about HIW's effectiveness, because the inspectorate had 'last visited ABMU [Abertawe Bro Morgannwg University Health Board] two years ago and not seen or reported on what would have been at the time highly visible issues of poor practice'. The fact that, apart from that case, hardly any participant could recall an issue that HIW overlooked during the inspection implies that HIW inspections are usually thorough.

A negative inspection report can help to create awareness of certain problems amongst managers or staff. External inspection reports seem to be particularly relevant for large LHBs with hierarchical gaps and impaired information flows between the top management and healthcare delivery. Yet, the interviews suggest that healthcare managers were already aware of most problems, before HIW inspections alerted them. This phenomenon has also been observed in England (Day & Klein, 2004; Walshe et al., 2014). Healthcare managers in Wales gave similar explanations on why they had not rectified the problems as their colleagues in England, who said that 'they were too close to the issue, or because practices had become normalised and routine' (Walshe et al., 2014, p. 67).

Though all interviewed LHB managers appeared to be committed to providing quality healthcare, the LHBs would cause financial damage to themselves, if they ceased to refer patients to their own hospitals after a negative report. LHBs' double role of commissioning and providing healthcare within their geographical borders is likely to cause a conflict of interest. As LHB managers explained, inspection reports can influence the LHBs' decisions to commission healthcare from other organisations in Wales or England. This however requires that decision makers become aware of inspection results, which does not always happen in a timely manner, as the interviews revealed.

6.3.4 Action plan

The interviews with HIW participants suggest that the quality of draft action plans has not generally improved. Enhanced action plans could provide an opportunity to increase regulatory effectiveness. It remains unclear why some healthcare organisations struggle to develop an acceptable improvement plan. If the difficulties are caused by a lack of experience rather than the shortage of time, HIW or other organisations could assist in the learning. HIW's peer reviewers with their expertise and double perspective could play a supportive role inside their healthcare organisations and beyond. HIW could benefit from involving the respective peer reviewers in the assessment of draft plans, in case HIW's review manager does not have sufficient expertise. A template with HIW's recommendations can provide the necessary guidance and structure, though, some organisations have criticised the duplication of work resulting from numerous improvement plans produced in different formats for internal and external purposes.

It is understandable that healthcare organisations that had already implemented the improvements complained about retrospective action plans, which HIW required them to submit after HIW's publishing the outdated reports. Producing outdated improvement plans does not increase regulatory effectiveness, but instead adds to the perceived regulatory burden (adverse impact) and undermines HIW's credibility. It would have been more transparent to inform the public that the healthcare organisation had resolved the problems. Likewise, HIW failed to 'reassure the public that remedial action had been taken' (Cardiff and Vale University Health Board, 2014, p. 4) by omitting to publish the agreed improvement plan together with the inspection report.

Even more concerning is the practice of some few NHS organisations to withhold actions or action planning until they receive HIW's recommendations in the final report. To start action planning and implementation based on the oral feedback – an approach, which independent hospitals and many other NHS organisations practice – exhibits a completely different attitude and culture. Here, small organisations have an advantage over the large organisations with more complicated internal approval and funding processes. Yet, not every improvement action requires extra funding and approval by the top management. This demonstrates the importance of contextual factors which are conducive for regulatory effectiveness.

The convoluted post-inspection summits that CQC arranges to launch the inspection reports and develop action plans do not seem to be a suitable alternative to the process in Wales (Walshe et al., 2014), though the summit would be an opportunity to bring internal and external stakeholders together.

6.3.5 Follow-up

The difficulties in delineating the responsibilities of follow-up between HIW, the Welsh government and other organisations, which have admittedly constituted a weakness in HIW's inspection regime, are not unique. Similarly, 'a lack of clarity' was reported regarding the follow-up of CQC inspections (Walshe et al., 2014, p. 72) and a 'significant gap' concerning the follow-up of warnings by the Norwegian Board of Health Supervision (European Partnership for Supervisory Organisations in Health Services and Social Care, 2012, p. 43). HIW seems to be caught in a dilemma: assuming the de-facto responsibility for the follow-up potentially increases the effectiveness of inspections but places a strain on HIW's resources. HIW's limited capacity and the opportunity cost drives HIW to conduct follow-up visits (only) 'when essential'. Yet, it remains unclear which issues or contextual factors make a follow-up visit essential.

Interviews with healthcare managers and some documentary evidence (Healthcare Inspectorate Wales, 2015c) support HIW's view point that the healthcare organisations do implement the improvement plans. The fact that almost all participants complained about non-existent or infrequent follow-up visits highlights an inherent risk. The fact that in all six cases of reported HIW follow-up inspections in 2014/2015 significant progress was noted supports the hypothesis that announced inspections can be effective. It does not prove that the two LHBs would have acted upon the recommendations similarly, had they not been pre-informed about the inspection dates. Besides, the follow-ups showed varying degrees of progress amongst the wards, declaring excellent progress only for one of the four wards revisited in 2014 (Jones, 2014) and requiring one of the two wards revisited in 2015 to complete a further improvement plan (Healthcare Inspectorate Wales, 2015e). HIW's (2015c) annual report presents the follow-up visit in March 2015 as evidence of HIW's impact, without mentioning that it was announced. HIW's (2016e) annual report for 2015/16 and several unannounced DECI (Healthcare Inspectorate Wales, 2015m) reports expressed disappointment about previous findings that had not brought improvements. This shows that HIW does follow-up previous findings (more than in the past), yet, not through a designated follow-up visit, but during the subsequent, routine inspection visit.

Systematic follow-up visits would provide the public with updated information (if reports are published immediately), and in case of positive progress help to restore confidence (if the public becomes aware of the positive findings).

6.4.6 Enforcement

The now formalised escalation process seems to work effectively: the first NHS organisation that was put under special measures, the highest escalation level, was in

2015 Betsi Cadwaladr University Health Board (Lewis-Parry, 2015; NHS Wales, 2015a). At the same time, four other NHS organisations were put under 'enhanced monitoring' (Welsh Government, 2016), the third-highest escalation level. In July 2017, Betsi Cadwaladr University Health Board was still in special measures and the status of three NHS organisations that were previously under 'enhanced monitoring' had been escalated to 'targeted intervention', the second highest escalation level (Welsh Government, 2017).

It can be safely assumed that the regulation of the escalation process, which defines the shared responsibilities of HIW, Welsh Audit Office and Welsh government, is a lesson learnt from the prominent failings in the UK. Although, as an HIW participant claimed, the informal interactions with the Welsh government have worked well in the past, they depended on personal initiative and bore the risk of failure due to unclear responsibilities.

The use of informal, tactical manoeuvres, which include threatening to close the hospital or requiring weekly meetings and progress updates (viz. 4.4.5 Enforcement, page 69), makes the inspectorate more powerful than it seems at first glance. The power games seemed to be effective due to the 'human factor' and the fear of negative publicity. This resembles the situation in England: Walshe and colleagues (2014, p. 70) cited a participant who concluded that CQC's 'informal enforcement, and external and internal leverage for change, are at least as important and perhaps more important than the use of formal regulatory powers'. Although HIW has regulatory powers over the independent sector, the inspectorate does not seem to need them. The reputation of inspected hospitals potentially benefits from positive inspection reports and HIW's advice on best practice (Healey, 2013), which independent hospital managers seek and accept.

6.4 Impact and Context-Mechanism-Outcome patterns

The numerous examples, which Healthcare managers and peer reviewers instanced, support the assumption that HIW inspections have resulted or contributed to positive changes at the healthcare organisations in Wales. HIW findings and recommendations have reportedly motivated LHB decision makers to revise priorities and financial allocations. The improvements were apparently determined by the thematic area of the inspection regime, but not confined to the inspected ward or hospital. HIW inspection findings have been used as an additional argument and leverage by internal stakeholders to convince decision makers or professional groups within their healthcare organisations. This experience corresponds with Walshe and colleagues' (2014, p. 71) findings that CQC's inspections 'added weight to influence and drive change' and Day and Klein's (2004) conclusion that CHI played a catalytic role. As the participants from

Wales asserted, the power of persuasion increases, when several external bodies require the same changes and when the media get involved.

Numerous contextual factors made these mechanisms work and generate positive outcomes (Pawson & Tilley 1997). At the healthcare organisations, the identified conducive contextual factors included understanding of and commitment to quality healthcare, professional (clinical and managerial) competencies, leadership, maturity and organisation culture, functioning quality and governance systems, flat organisational hierarchies with communication flows and informed decision making as well as a customer/patient focus. Many of these factors coincide with the findings Kringos and colleagues (2015) made in their systematic review on the effectiveness of hospital quality improvement strategies.

Amongst the factors which appeared to jeopardise the improvement of healthcare quality at the healthcare organisations in Wales were an environment where managers and staff feel exhausted and powerless and thus become used to inadequate care and conditions. Here particularly the shortage of finance and staff, the high workload and the perceived 'unchangeable' physical hospital infrastructure desensitised staff and managers.

Influencing financial decisions does not necessarily require formal power. The redirection of existing resources bears, however, the unintended risk of withdrawing funds from other important areas, which are not the subject of the ongoing inspection regime, as the Trusted-to-care report anticipated (Andrews & Butler, 2014). This potential negative impact has not been identified in the interviews of this study. However, some NHS managers referred to idealistic interpretations and recommendations such as the provision of hot food in the A&E department, which would have required shifting funds from other (more priority) areas. Most of the questionable recommendations did not appear later in the inspection reports, which reflects HIW's sound judgement. It is the duty of the managers to weigh up the circumstances and apply common sense in their decisions. Contrary to healthcare professionals, managers with financial responsibility cannot ignore the overall budget restrictions, competing needs and opportunity cost.

That different review bodies sometimes come to different conclusions raises questions about the validity and reliability of inspection methods. Inspection methodologies should be assessed concerning their effectiveness, rather than deriving from mere opinions about what constitutes the best approach (Bundred & Grace, 2008). Though, HIW has recently strengthened its data analysis capacity and conducted follow-up inspections, more systematic evaluation would help to determine the effectiveness of HIW's inspection regimes and methodologies. This is not dissimilar to other review bodies, which lack a systematic process to assess the effectiveness and possible impact of

activities (European Partnership for Supervisory Organisations in Health Services and Social Care, 2012).

HIW's limited inspection activities during 2012-14 reportedly encouraged LHBs to recognise their responsibility and install internal assurance systems. This was not HIW's deliberate intention, but an unintended positive effect. Even if HIW had more resources at their disposal, it is unrealistic to have sufficient inspectors and inspections to monitor every nurse and doctor (Flynn, 2012). Moreover, an increase of HIW's funding would mean a decrease of financial resources available for other areas, such as healthcare provided by the NHS.

The revelation that healthcare quality varies within a hospital (Berwick et al., 2013), which HIW and healthcare managers recognised during this study, seems to have impacted on the design of internal and external inspections and may increase future effectiveness.

The interviews manifested that improvements resulting from investments in furniture or interior decoration were comparatively easy to achieve. Much more effort and time require changes in individual and group behaviour, for example the hand hygiene or clinical procedures. Though some improvements were instanced, it remains unclear how far HIW's inspections positively affected behavioural changes.

Irrespective of the above mentioned positive changes, HIW influence on improvements in the NHS is limited. HIW inspections repeatedly detect the same problems amongst NHS hospitals and several LHBs had to be put under 'targeted intervention' or 'special measures' (Welsh Government, 2017). Although improvement and deterioration are, allegedly, likely to occur together (Boyne, 2003), more analysis is needed regarding the structural and organisational barriers and drivers of positive change in Welsh hospitals.

6.5 Conclusion

This chapter has shown that regulatory effectiveness depends on numerous factors and mechanisms. Some of them can be actively managed by the inspectorate such as the inspection methods and tools, debriefing and reporting, others are not or only partly in the hands of the inspectorate or review managers such as setting standards, self-assessments, access to data, action planning and enforcement. The budget, which the Welsh government allocates, defines the boundaries in which HIW can recruit and train staff and reviewers, conduct hospital inspections and perform the many other tasks according to its remit. The moderate impact, which HIW's inspections seem to have on healthcare improvement, stems from various mechanisms which differ in their effectiveness across the various inspection regimes and between large NHS healthcare organisations and the small independent hospitals. As there is not one ideal inspection

regime that fits all settings and times, HIW needs to keep adapting its strategies and tactics before, during and after the on-site inspection.

This study identified various mechanisms which contributed to regulatory effectiveness in Wales, amongst them the following: First, active involvement of healthcare managers in the development of healthcare standards supports the recognition of what the standards are 'trying to achieve' and ownership. Second, the communication between HIW and the healthcare managers helps to create common understanding of requirements, professional relationships and mutual respect, which can contribute to the success of the registration and effectiveness of later inspections. Third, HIW's autonomy in selecting the inspection sites was identified as a factor for potential effectiveness, because it underlines HIW's professional independence and thus increases credibility amongst the healthcare community. Fourth, managers with a nursing background acknowledge (and are therefore more inclined to follow) thorough scrutiny, validated findings, balanced feedback and recommendations by an inspection team which includes clinical professionals, who specialise in the respective area. Fifth, intrinsic factors, such as commitment to quality care, as well as extrinsic factors, such as the fear of being exposed in inspection reports and media, motivate compliant behaviour. Sixth, hospital managers occasionally use reviews and recommendations from credible, external organisations as 'levers for change' to convince other stakeholders to change behaviour or allocate the necessary resources for compliance and improvement. Seventh, senior managers, who are far from frontline provision, appreciate external reviews as a reality check of internal governance and quality assurance mechanisms.

The following, final chapter will summarise the main conclusions of this thesis and recommendations for modifications in HIW's inspection regimes.

7 Conclusions

The final chapter summarises the key findings of this thesis, reflects on methodological limitations and highlights implications for future research and practice.

Following a theory-driven realist approach, this thesis aimed to evaluate the strengths and weaknesses of HIW's acute hospital inspection regimes. The document review and interviews with research participants from HIW and healthcare organisations in Wales helped to establish how HIW's inspection regimes had been implemented and what problems were encountered during implementation. Applying a three-stage theoretical framework, the study examined the elements and mechanisms which have shown to be effective in particular settings and assessed what modifications are likely to improve effectiveness. The framework informed the design of data collection tools and structured the data analysis.

7.1 Summary of findings

The interviews did not detect unanimous, preconceived assumptions amongst HIW managers and reviewers on how particular elements of the inspection regimes are supposed to become effective. This is perhaps not surprising, given that inspecting constitutes for most HIW managers and reviewers a role or job rather than a profession. In the endeavour to reconstruct the underlying change mechanisms, which forms an essential part of the theory-driven approach, the researcher consulted various sources, including hospital managers and evaluation literature. Due to their dual perspective, contributions by peer reviewers and HIW managers with clinical experience proved to be particularly valuable.

The evaluation showed that various political, socio-economic and other contextual factors influenced the design and implementation of HIW's hospital inspections. This includes HIW's funding. The differences in regulation between NHS and independent hospitals in Wales seem entirely politically-driven. HIW's relocation and high turnover of staff in 2012-2013, which were largely influenced by external factors, undermined its ability to conduct inspections, caused severe delays in reporting and damaged its reputation. Although no evidence was found that lost or delayed reports had caused any (other) damage, delays in reporting can potentially impede improvement when the inspected organisation waits for HIW's report before taking actions. With its new staff, HIW has improved its capacity to analyse data, conduct inspections and issue reports sooner.

HIW uses various mechanisms and tactics to direct, detect and enhance compliance with standards. Many aspects of its inspection regimes, such as standard-setting, data-

exchange, follow-up and enforcement, require close cooperation with the government and other review bodies. HIW has rarely faced the need to use its rather restricted enforcement powers, but predominantly relies on its credibility as an impartial, professional authority and, if necessary, on informal, tactical manoeuvres to effect necessary change.

HIW's regulatory effectiveness largely depends on the cooperation with the inspected health organisations prior, during and after the on-site inspections. A hospital manager may approach HIW concerning a suspected problem. Hospital staff (confidentially) share internal data and information with inspection teams. Senior managers of large NHS organisations use external inspections to identify problems which they struggle to spot due to the hierarchical gap and geographical distance. Hospital managers in Wales appreciate unannounced inspections as an authentic depiction of the situation on an inspected ward (spot-check), yet, the distinction between unannounced and announced inspections can be ambiguous. Certain stakeholders use inspection reports as levers to address an (already) identified problem, especially when other review bodies or stakeholders, including the media, require the same changes.

While some improvements, particularly concerning hospital infrastructure, have been associated with HIW's inspections, other problems keep recurring in NHS hospitals. Several NHS health boards in Wales have been put under 'targeted intervention' and one has been in 'special measures' since 2015. This suggests that HIW's impact on NHS hospital care has been moderate. Inspection results are reportedly more positive in small, specialised healthcare organisations with fewer hierarchical levels, dedicated managers and sufficient funding.

7.2 Contribution to research

Many findings of this evaluation concur with previous studies, particularly Walshe and colleagues' (2014) evaluation of CQC inspections and Day and Klein's (2004) evaluation of CHI inspections. This includes (i) the catalytic effect of inspections, which induce self-examination and pre-emptive actions, and (ii) the extra-leverage of external inspections, which help committed internal stakeholders to address notorious problems. The study also noted appreciation of targeted feedback amongst many hospital managers, which Walshe and colleagues (2014, p. 67) refer to as 'free consultancy'. Yet, predominantly independent hospital managers were said to proactively seek advice for improvement from reviewers during HIW's inspections. The suggestion that minimum standards tend to drive mediocrity seems to be valid for large NHS bodies. The positive examples of small, specialised (independent and NHS) hospitals in Wales show that minimal standards do not necessarily act as a 'barrier for innovation' (Walshe, 2003, p. 47) in

well-performing hospitals. The success of minimum standards in the independent sector can partly be attributed to the close involvement of hospital managers in the development of standards process that Walshe (2003, p. 19) described.

This research study is the first to investigate and evaluate HIW's inspection regimes. Previous evaluations have predominantly examined particular inspection regimes in England, such as the above-mentioned evaluations of CHI and CQC's inspection regimes, which were commissioned by the review bodies. The evaluation of HIW's inspection regimes did not restrict itself to one inspection regime only but examined inspections of acute NHS and non-NHS hospitals in Wales. The comparison of how the different elements are implemented and work across the different regimes and settings generated valuable findings, which can, in a very modest way, contribute to inspection theory and inform future practice and research.

7.3 Limitations and implications for research

The specific circumstances in Wales and the nature of this research mean that the findings of this study cannot be automatically transferred to other inspection regimes. The methodology chapter (viz. 3.5 Challenges of the research design and implementation) highlighted various challenges and limitations. The complexity of healthcare and healthcare inspections with many, often interrelated variables make it virtually impossible to objectively relate particular outcomes (e.g. improvements in healthcare) to one single intervention (i.e. hospital inspection). By inviting the two major stakeholder groups, i.e. the inspectorate and the inspected healthcare organisations, the study aimed to capture the most important aspects and insights. The efforts to balance the recruitment of research participants amongst the hospital representatives regarding their professional background and gender were only partly successful. The self-selection of participants and non-participation of patients, lay reviewers and medical professionals in the evaluation may have caused bias.

Further studies of similar inspection regimes may help to refine the findings of this evaluation. A mixed-methodology approach, which incorporates participant observation and quantitative data from the inspectorate and the inspected organisations, would strengthen the research design. A broader contingent of participants, including medical professionals, lay reviewers and patients would help to view the inspections from a different perspective and most likely generate new findings.

This study examined the process stages, elements and mechanisms of HIW's acute hospital inspection regimes, but, due to time constraints and complexity, it did not research them in every detail. A more detailed examination will be necessary to establish

the influence of particular factors in specific settings. This will include, for example, how the selection of inspection sites can be optimised or how inspection reporting can be improved to become more effective.

7.4 Lessons learnt for regulatory policy and practice

Given the complexity of healthcare and moderate impact of external inspections, governmental decision-makers and hospital managers are advised to arrange for governance and quality systems which comprise different, complementary approaches, including internal and external peer review schemes. Continued cooperation amongst review bodies in Wales can be instrumental in improving coordination of inspections. HIW may wish to establish mechanisms to periodically review, evaluate, adapt or develop (new) inspection regimes or elements, methods and tools with the aim to maintain or increase regulatory effectiveness.

The findings of this study suggest some options for improvement, amongst them are the following:

- Access to and analysis of real-time, ward-specific data and multi-ward inspections could increase the potential to detect non-compliance.
- Selecting expert-reviewers with the matching clinical skills, including medical professionals, can further increase the hospitals' acceptance of advice and critical findings and thus their willingness to act upon those.
- A higher portion of unannounced out-of-hour visits, as in HIW's mental healthcare inspections, can serve as a further reality check for hospital managers.
- Systematic follow-up of improvement plans, ideally involving the Welsh government, would keep hospitals on their toes and assure the public that healthcare services are sufficiently safe.

As there is no one-size-fits-all inspection regime, inspectorates need to find the right mix and balance between alternative options and keep adapting regimes.

8 References

- Abertawe Abertawe Bro Morgannwg University Health Board. (2014). HIW - report on spot check on Morriston's emergency department (A&E) [online]. Retrieved February 22, 2016, from <http://www.wales.nhs.uk/sitesplus/863/news/32645>
- Action against Medical Accidents. (2013). *Implementation of patient safety alerts in Wales*. Croydon: Action against Medical Accidents.
- Adil, M. (2008). Risk-based regulatory system and its effective use in health and social care. *The Journal of the Royal Society for the Promotion of Health*, 128(4), 196–201.
- Anderson, G. J., & Arsenault, N. (1998). *Fundamentals of educational research*. London: Falmer Press.
- Andrews, J., & Butler, M. (2014). *Trusted to care. An independent review of the Princess of Wales hospital and Neath Port Talbot hospital at Abertawe Bro Morgannwg University Health Board*. Stirling: Dementia Services Development Centre and The People Organisation.
- Argy, S., & Johnson, M. (2003). *Mechanisms for improving the quality of regulation: Australia in an international context*. Melbourne: Productivity Commission.
- Arthur, S., & Nazroo, J. (2003). Designing fieldwork strategies and materials. In J. Ritchie & J. Lewis (Eds.), *Qualitative research practice: a guide for social science students and researchers* (pp. 109–137). London: Sage Publications Ltd.
- Baldwin, R., & Black, J. (2008). Really responsive regulation. *The Modern Law Review*, 71(1), 59–94.
- Baldwin, R., Cave, M., & Lodge, M. (2012). *Understanding regulation: theory, strategy, and practice* (2nd ed.). Oxford: Oxford University Press.
- Bardsley, M. (2016). Learning how to make routinely available data useful in guiding regulatory oversight of hospital care. *BMJ Quality & Safety, OnlineFirst*(April), 1–3.
- Bate, P., Robert, G., Fulop, N., Øvretveit, J., & Dixon-Woods, M. (2014). *Perspectives on context*. London: The Health Foundation.
- BBC. (2015). Hospital ward inspection downgraded, Welsh Tories claim [online]. Retrieved August 12, 2015, from <http://www.bbc.co.uk/news/uk-wales-politics-33810042>
- Beaussier, A.-L., Demeritt, D., Griffiths, A., & Rothstein, H. (2015). *Why risk-based regulation of healthcare quality in the NHS cannot succeed*. London: King's College London.
- Beaussier, A.-L., Demeritt, D., Griffiths, A., & Rothstein, H. (2016). Accounting for failure: risk-based regulation and the problems of ensuring healthcare quality in the NHS. *Health, Risk & Society*, 18(3/4Be), 1–20.
- Benson, L., Boyd, A., & Walshe, K. (2004). *Learning from CHI: the impact of healthcare regulation*. London: Commission for Health Improvement and Manchester Centre for Healthcare Management.
- Berry, W. D. (1982). Theories of regulatory impact: the roles of the regulator, the regulated, and the public. *Review of Policy Research*, 1(3), 436–441.
- Berwick, D. M. (2002). A user's manual for the IOM's "Quality Chasm" report. *Health Affairs*, 21(3), 80–90.

- Berwick, D. M., Bibby, J., Bisognano, M., Callaghan, I., Dalton, D., Dixon-Woods, M., Vincent, C. (2013). *A promise to learn – a commitment to act. Improving the safety of patients in England*. London: The National Advisory Group on the Safety of Patients in England.
- Berwick, D. M., James, B., & Joel Coye, M. (2003). Connections between quality measurement and improvement. *Medical Care*, 41(1), 1-30-1-38.
- Betsi Cadwaladr University Health Board. (2013). *Health Inspectorate Wales independent review of patient care at Ysbyty Glan Clwyd: update of actions undertaken since the review February 2012*. Bangor: Betsi Cadwaladr University Health Board, (Board paper 24.1.13 Item 13/016.2).
- Betsi Cadwaladr University Health Board. (2016). Healthcare Inspectorate Wales (HIW) reports [online]. Retrieved April 10, 2017, from <http://www.wales.nhs.uk/sitesplus/861/page/79150/>
- Bevan, G. (2008). Changing paradigms of governance and regulation of quality of healthcare in England. *Health, Risk & Society*, 10(1), 85–101.
- Bevan, G., & Cornwell, J. (2006). Structure and logic of regulation and governance of quality of health care: was OFSTED a model for the Commission for Health Improvement? *Health Economics Policy Law*, 44, 343–370.
- Black, J. (2001). Managing discretion. *ARL Conference Papers: Penalties: Policy, Principles and Practice in Government Regulation*, 44(June), 1–40.
- Black, J. (2002). Critical reflections on regulation. *Australian Journal of Legal Philosophy*, 27(1), 1–36.
- Black, J., & Baldwin, R. (2012). When risk-based regulation aims low: A strategic framework. *Regulation and Governance*, 6(2), 131–148.
- Boaden, R. (2011). Quality improvement in healthcare. In K. Walshe & J. Smith (Eds.), *Healthcare Management* (pp. 488–514). Maidenhead: Open University Press.
- Board of Community Health Councils in Wales. (2014). *Annual report 2014/15*. Cardiff: Community Health Council.
- Bowling, A. (2005). Mode of questionnaire administration can have serious effects on data quality. *Journal of Public Health*, 27(3), 281–291.
- Bowling, A. (2009). *Research methods in health. Investigating health and health services*. Maidenhead: Open University Press.
- Boyne, G. A. (2003). What is public service improvement ? *Public Administration Research*, 81(2), 211–228.
- Boyne, G. A., Day, P., & Walker, R. (2002). The evaluation of public service inspection: a theoretical framework. *Urban Studies*, 39(7), 1197–1212.
- Braithwaite, J. (2008). *Regulatory capitalism: how it works, ideas for making it work better*. Cheltenham: Edward Elgar Publishing.
- Braithwaite, J. (2011). The essence of responsive regulation. *UBC Law Review*, 44(3), 475–520.
- Braithwaite, J. (2016). *Restorative justice and responsive regulation: the question of evidence* (RegNet Working Paper, No. 51). School of Regulation and Global Governance (RegNet).
- Braithwaite, J., & Braithwaite, V. (1995). The politics of legalism: rules versus standards in nursing-home regulation. *Social and Legal Studies*, 4, 307–44.

- Braithwaite, J., & Hong, S. H. (2015). The iteration deficit in responsive regulation: are regulatory ambassadors an answer? *Regulation and Governance*, 9(1), 16–29.
- Braithwaite, J., Walker, J., & Grabovsky, P. (1987). An enforcement taxonomy of regulatory agencies. *Law and Policy*, 9(3), 323–352.
- Brook, R. H., McGlynn, E. A., & Shekelle, P. G. (2000). Defining and measuring quality of care: A perspective from US researchers. *International Journal for Quality in Health Care*, 12(4), 281–295.
- Bundred, S., & Grace, C. (2008). Holistic Public Services Inspection. In H. Davis & S. Martin (Eds.), *Public Services Inspection in the UK* (pp. 102–119). London: Jessica Kingsley Publishers.
- Butterfield, R., McCormick, B., Anderson, R., Ball, J., White, J., & Eleftheriades, C. (2012). *Quality of NHS care and external pathway peer review*. London: Centre for Health Service Economics and Organisation.
- Cairns, A. (2013). *Inquiry into the work of Healthcare Inspectorate Wales*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- Cardiff and Vale University Health Board. (2014). Minutes of a meeting of the quality, safety and experience committee held at 09.00 on Tuesday 1st April 2014 in the meeting room, headquarters, UHW [online]. Retrieved September 2, 2015, from https://www.cardiffandvaleuhb.wales.nhs.uk%2Fopendoc%2F241626&usg=AFQjCNH4f_zZ97LZf7QxL0ZCotlhqOVhNQ
- Care & Social Services Inspectorate Wales, Estyn, HIW, & Wales Audit Office. (2011). *Developing our work together in a climate. A paper on inspection, audit and regulation in Wales*. Cardiff: Care and Social Services Inspectorate Wales, Estyn, Healthcare Inspectorate Wales and Wales Audit Office.
- Carnino, A. (2000). Management of safety, safety culture and self assessment. In *Proceedings of the International Conference on Nuclear Energy in Central Europe. Bled, 11-14 September 2000* (pp. 1–15). Bled.
- Chen, H., & Rossi, P. H. (1987). The theory-driven approach to validity. *Evaluation and Program Planning*, 10, 95–103.
- Clarke, A., & Dawson, R. (1999). *Evaluation research: an introduction to principles, methods, and practice*. London: Sage Publications Ltd.
- Commission for Healthcare Audit and Inspection. (2009). *The Healthcare Commission 2004 - 2009. Regulating healthcare - experience and lessons*. London: Commission for Healthcare Audit and Inspection.
- Community Health Councils. (2013). *The work of the Healthcare Inspectorate Wales. Evidence from Community Health Councils - HIW 30*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- Cooper, S. (2005). *Inspection methodology: cancer networks*. Caerphilly: Healthcare Inspectorate Wales.
- Coryn, C. L. S., Noakes, L. A., Westine, C. D., & Schroeter, D. C. (2010). A systematic review of theory-driven evaluation practice from 1990 to 2009. *American Journal of Evaluation*, 32(2), 199–226.
- Cowing, M., Davino-Ramaya, C. M., Ramaya, K., & Szmerekovsky, J. (2009). Health care delivery performance: service, outcomes, and resource stewardship. *The Permanente Journal*, 13(4), 72–8.
- Creswell, J. W. (2009). *Research design: qualitative, quantitative, and mixed methods*

- approaches* (3rd ed.). London: Sage Publications.
- Cwm Taf University Health Board. (2014). Framework for partnership dignity visits (May 2014) [online]. Retrieved April 6, 2016, from <http://www.cwmtafuhb.wales.nhs.uk/news/32912>
- Davis, H., & Martin, S. (2008). The rise of public services inspection. In H. Davis & S. Martin (Eds.), *Public services inspection in the UK* (pp. 7–18). London: Jessica Kingsley Publishers.
- Day, P., & Klein, R. (2004). *The NHS improvers. A study of the Commission for Health Improvement*. London.
- Denzin, N., & Lincoln, Y. S. (2003). The discipline and practice of qualitative research. In N. Denzin & Y. S. Lincoln (Eds.), *Collecting and interpreting qualitative materials* (2nd ed., pp. 1–60). London: Sage Publications Ltd.
- Dixon-Woods, M., Myles, L., Bion, J., & Tarrant, C. (2012). What counts? An ethnographic study of infection data reported to a patient safety program. *Milbank Quarterly*, 90(3), 548–91.
- Dixon, A., Foot, C., & Harrison, T. (2012). *Preparing for the Francis report. How to assure quality in the NHS*. London: The King's Fund.
- Dixon, J. (2011). The policy of health care and health care policy process: implications for management. In K. Walshe & J. Smith (Eds.), *Healthcare management* (2nd ed., pp. 13–36). Maidenhead: Open University Press.
- Dixon, N., & Pearce, M. (2011). *Guide to using quality improvement tools to drive clinical audits*. London: Healthcare Quality Improvement Partnership.
- Dodds, A., & Kodate, N. (2011). Accountability, organisational learning and risks to patient safety in England: conflict or compromise? *Health, Risk & Society*, 13(4), 327–346.
- Donabedian, A. (2005). Evaluating the quality of medical care. *The Milbank Quarterly*, 83(4), 691–729.
- Donaldson, S. I. (2007). *Program theory-driven evaluation science: strategies and applications*. New Delhi: Lawrence Erlbaum Associates.
- Downe, J., & Martin, S. (2007). Regulation inside government: Processes and impacts of inspection of local public services. *Policy and Politics*, 35(2), 215–232.
- Duerden, D. M., & Hopkins, A. (2013). *The work of the Healthcare Inspectorate Wales. Evidence from the Betsi Cadwaladr University Local Health Board – HIW 07*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- European Partnership for Supervisory Organisations in Health Services and Social Care. (2012). *Report of a peer evaluation of The Norwegian Board of Health Supervision (Statens helsetilsyn)*. Den Haag: European Partnership for Supervisory Organisations in Health Services and Social Care.
- Flick, U. (2011). *Qualitative Sozialforschung: eine Einführung* (4th ed.). Reinbek: Rowohlt Taschenbuch Verlag.
- Flodgren, G., Pomey, M.-P., Taber, S. A., & Eccles, M. P. (2011). Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes. *Cochrane Database of Systematic Reviews*, (11).
- Flynn, N. (2012). *Public sector management* (6th ed.). London: Sage Publications Ltd.

- Francis, R. (2013). *Report of the Mid Staffordshire NHS Foundation Trust public inquiry*. London: The Stationery Office.
- Gibbs Brown, J. (1999). *The external review of hospital quality. A call for greater accountability*. Boston: Department of Health and Human Services, Office of Inspector General.
- Gilad, S. (2010). It runs in the family: meta-regulation and its siblings. *Regulation and Governance*, 4(4), 485–506.
- Gray, J. A. M. (2001). *Evidence-based healthcare*. London: Churchill Livingstone.
- Green, J., & Thorogood, N. (2004). *Qualitative methods for health research*. London: Sage Publications Ltd.
- Griffiths, A., Beaussier, A.-L., Demeritt, D., & Rothstein, H. (2016). Intelligent monitoring? Assessing the ability of the Care Quality Commission's statistical surveillance tool to predict quality and prioritise NHS hospital inspections. *BMJ Quality & Safety, Online*(April), 1–11.
- Grimshaw, J. M., McAuley, L. M., Bero, L. a, Grilli, R., Oxman, A. D., Ramsay, C., ... Zwarenstein, M. (2003). Systematic reviews of the effectiveness of quality improvement strategies and programmes. *Quality & Safety in Health Care*, 12(4), 298–303.
- Grol, R., & Wensing, M. (2004). What drives change? Barriers to and incentives for achieving evidence-based practice. *Medical Journal of Australia*, 180(6 SUPPL.), 57–60.
- Guba, E. G. (1990). The alternative paradigm dialog. In E. G. Guba (Ed.), *The paradigm dialog* (Vol. 1, pp. 17–27). London: Sage Publications Ltd.
- Gunningham, N. (2015). *Compliance, deterrence and beyond*. Canberra: Regulatory Institutions Network, Australian National University.
- Gunningham, N., Grabovsky, P., & Sinclair, D. (1998). *Smart regulation. Designing environmental policy*. Oxford: Oxford University Press.
- Ham, C. (2014). *Reforming the NHS from within. Beyond hierarchy, inspection and markets*. London: The King's Fund.
- Hammersley, M. (1992). *What is wrong with ethnography*. London: Routledge.
- Hampton, P. (2005). *Reducing administrative burdens: effective inspection and enforcement*. London: HM Treasury.
- Hawkes, N. (2011). The Care Quality Commission: unfit for purpose? *Bmj*, 343(dec14 2), d8034–d8034.
- Healey, K. (2013). *The work of the Healthcare Inspectorate Wales. Evidence from Nuffield Health - HIW 12*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- Health and Social Care Committee. (2014). *The work of Healthcare Inspectorate Wales*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- Healthcare Inspectorate Wales. (2005). *Inspection methodology: local health board*. Caerphilly: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2006). *All Wales maternity services review*. Caerphilly: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2007a). *Annual report 2006-2007*. Caerphilly:

Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2007b). *Report on infection control - findings and themes*. Caerphilly: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2008). *Hospital cleanliness spot check. Direct observation audit tool* (No. Audit tool version 1.0). Caerphilly.

Healthcare Inspectorate Wales. (2009). *Staff questions. Mental health services for older People. Healthcare standards 2009. Privacy and dignity 2009*. Caerphilly: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2011). *St Joseph's Hospital. Harding Avenue. Malpas. Newport. Gwent. NP20 6ZE. Inspection 2010-2011*. Merthyr Tydfil: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2012a). *An independent review of patient care at Ysbyty Glan Clwyd*. Caerphilly: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2012b). *Annual report 2010-2011*. Caerphilly: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2012c). *Three-year programme 2012-2015*. Caerphilly: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2013a). *Guidance on fees payable by independent healthcare providers and private dentists registered with Healthcare Inspectorate Wales: Registration fees. Fees to vary or remove a condition of registration. Annual fees*. Caerphilly: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2013b). *Inspection Wales*. Retrieved October 15, 2013, from <http://www.inspectionwales.com/Home.aspx>

Healthcare Inspectorate Wales. (2013c). *The work of the Healthcare Inspectorate Wales. Evidence from the Healthcare Inspectorate Wales*. Caerphilly: National Assembly for Wales, Health and Social Care Committee.

Healthcare Inspectorate Wales. (2014a). *Annual report 2013-2014*. Merthyr Tydfil: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2014b). *Dignity and Essential Care Inspection (DECI) report for Prince Philip Hospital, Hywel Dda University Health Board published [online]*. Retrieved March 30, 2016, from <http://www.hiw.org.uk/news/34044>

Healthcare Inspectorate Wales. (2014c). *Dignity and Essential Care Inspection (unannounced). Cwm Taf University Health Board - Ysbyty Cwm Rhondda Hospital - Ward B2*. Merthyr Tydfil: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2014d). *Infection prevention and control inspections [online]*. Retrieved January 11, 2016, from <http://www.hiw.org.uk/infection-prevention-and-control-inspect>

Healthcare Inspectorate Wales. (2014e). *Learn more about us [online]*. Retrieved February 9, 2016, from <http://www.hiw.org.uk/learn-more-about-us-1>

Healthcare Inspectorate Wales. (2014f). *Operational plan 2014-2015*. Merthyr Tydfil: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2014g). *Unannounced Dignity and Essential Care Inspection, including a Cleanliness Spot Check. Cwm Taf University Health Board. Prince Charles Hospital. Ward 3*. Merthyr Tydfil: Healthcare Inspectorate Wales.

Healthcare Inspectorate Wales. (2015a). *About us [online]*. Retrieved March 7, 2016,

from <http://www.hiw.org.uk/about-us>

- Healthcare Inspectorate Wales. (2015b). *Aneurin Bevan University Health Board annual report from Healthcare Inspectorate Wales 2014/15*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015c). *Annual report 2014–15*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015d). *Betsi Cadwaladr University Health Board annual report from Healthcare Inspectorate Wales*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015e). *Dignity and Essential Care follow-up inspection (announced)*. Cardiff and Vale University Health Board: Ward B6 Trauma and Orthopaedic, University Hospital of Wales, Cardiff. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015f). *Dignity and Essential Care Inspection (unannounced)*. Aneurin Bevan University Health Board: Nevill Hall, accident and emergency department. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015g). *Dignity and Essential Care Inspection (unannounced)*. Aneurin Bevan University Health Board: St Woolos Hospital, Penhow Ward. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015h). *Dignity and Essential Care Inspection (unannounced)*. Aneurin Bevan University Health Board. Royal Gwent Hospital, Ward C7 West. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015i). *Dignity and Essential Care Inspection (Unannounced)*. Betsi Cadwaladr University Health Board: Ysbyty Glan Clwyd. Ward 19a (gynaecology and breast care). Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015j). *Dignity and Essential Care Inspection (unannounced)*. Cwm Taf University Health Board, Prince Charles Hospital, Ward 8. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015k). *Dignity and Essential Care Inspection (unannounced)*. Cwm Taf University Health Board: Ysbyty Cwm Cynon, Ward 3 (trauma and orthopedics-rehabilitation). Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015l). *Dignity and Essential Care Inspection (unannounced)*. Powys teaching Health Board, Brecon War Memorial Hospital, Epynt ward. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015m). *Dignity and Essential Care Inspection (unannounced)* Abertawe Bro Morgannwg University Health Board, Singleton Hospital, Ward 6. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015n). *Dignity and Essential Care Inspections 2014–15. Thematic report*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015o). *Health and care standards inspection (unannounced)*. Cardiff and Vale University Health Board: St David's Hospital, Elizabeth Ward. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015p). *HIW's assessment of risk process*. Merthyr Tydfil: Healthcare Inspectorate Wales.

- Healthcare Inspectorate Wales. (2015q). *Hospital Inspection (Unannounced) Cardiff and Vale University Health Board: Noah's Ark Children's Hospital, Island Ward, Pelican Zone, Owl Ward and Paediatric Critical Care Unit (PCCU)*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015r). *Job description*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015s). *Operational plan 2015-16*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015t). *Strategic plan 2015-18*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2015u). *Velindre NHS Trust annual report from Healthcare Inspectorate Wales 2014-15*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2016a). *Annual report 2015-16*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2016b). *Hospital Inspection (unannounced). Aneurin Bevan University Health Board: Royal Gwent Hospital, St Woolos Hospital*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2016c). *Hospital Inspection (unannounced) Betsi Cadwaladr University Health Board: Community Hospitals – Penrhos Stanley, Mold and Denbigh*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2016d). *Independent external reviews of homicides: an evaluation of reviews undertaken by Healthcare Inspectorate Wales since 2007*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2016e). *NHS hospital inspections. Annual report 2015-2016*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2016f). The peer review programme [online]. Retrieved from <http://hiw.org.uk/about/whatwedo/inspect/peerreviewprogramme/?lang=en>
- Healthcare Inspectorate Wales. (2016g). *Using intelligence to support risk based activity*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2017a). *Enhancing our use of intelligence*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2017b). *How does HIW inspect the NHS?* Merthyr Tydfil: Healthcare Inspectorate Wales.
- Healthcare Inspectorate Wales. (2017c). Volunteer Lay Reviewer for Healthcare Inspectorate Wales (HIW) [online]. Retrieved January 26, 2016, from <http://hiw.org.uk/docs/hiw/guidance/170609layreviewerroleen.docx>
- Healy, J. (2016). *Improving health care safety and quality: reluctant regulators (law, ethics and governance)*. Abingdon: Routledge.
- Hibbard, J. H., Stockard, J., & Tusler, M. (2005). Hospital performance reports: impact on quality, market share, and reputation. *Health Affairs*, 24(4), 1150–1160.
- Hilarion, P., Suñol, R., Groene, O., Vallejo, P., Herrera, E., & Saura, R. M. (2009). Making performance indicators work: the experience of using consensus indicators for external assessment of health and social services at regional level in

- Spain. *Health Policy*, 90(1), 94–103.
- Hood, C., James, O., & Scott, C. (2000). Regulation of Government : Has It Increased , Is It Increasing , Should It Be Diminished ? *Public Administration*, 78(2), 283–304.
- Hovlid, E., Høifødt, H., Smedbråten, B., & Braut, G. S. (2015). A retrospective review of how nonconformities are expressed and finalized in external inspections of health-care facilities. *BMC Health Services Research*, 15(1), 405.
- Hutt, J. (2004). *Cabinet statement. Health and Social Care (Community Health and Standards) Act 2004*. Cardiff: Welsh Assembly Government.
- Hysong, S. J. (2009). Meta-Analysis: audit & feedback features impact effectiveness on care quality. *Med Care*, 47(3), 356–363.
- International Finance Corporation. (2010). *A self-assessment guide for health care organizations*. Washington: International Finance Corporation.
- Ivers, N., Jamtvedt, G., Flottorp, S., Young, J. M., Odgaard-Jensen, J., French, S. D., ... Oxman, A. D. (2012). *Audit and feedback: effects on professional practice and healthcare outcomes (review)*. *Cochrane database of systematic reviews*. Toronto: John Wiley & Sons.
- James, B. C. (1989). *Quality management for health care delivery. The Hospital Research and Educational Trust*. Chicago: Quality Measurement and Management Project (QMMP).
- James, O. (2000). Regulation inside government: public interest justifications and regulatory failures. *Public Administration*, 78(2), 327–343.
- Jenkinson, C., Coulter, A., & Bruster, S. (2002). The Picker patient experience questionnaire: development and validation using data from in-patient surveys in five countries. *International Journal for Quality in Health Care*, 14(5), 353–358.
- Jewell, T., & Wilkinson, J. (2008). Health and social care regulation in Wales: an integrated system of political, corporate and professional governance for improving public health. *Journal of the Royal Society for the Promotion of Health*, 128(6), 306–312.
- Johns, C., & Lock, D. (2008). Inspection of adult and children's social care. In H. Davis & S. Martin (Eds.), *Public services inspection in the UK* (pp. 37–51). London: Jessica Kingsley Publishers.
- Johnson, R. B., & Onwuegbuzie, A. J. (2004). Mixed methods research: a research paradigm whose time has come. *Educational Researcher*, 33(7), 14–26.
- Jones, A. (2014). *Dignity and Essential Care Inspection 17 and 18 April 2018*. Merthyr Tydfil: Healthcare Inspectorate Wales.
- Jones, C. (2004). *Inspection methodology: mental health services*. Caerphilly: Healthcare Inspectorate Wales.
- Kagan, R. A., & Scholz, J. T. (1984). The “criminology of the corporation” and regulatory enforcement strategies. In K. Hawkins & J. M. Thomas (Eds.), *Enforcing regulation* (pp. 67–95). Boston: Kluwer-Nijhoff.
- Kaplan, H. C., Provost, L. P., Froehle, C. M., & Margolis, P. A. (2012). The model for understanding success in quality (MUSIQ): building a theory of context in healthcare quality improvement. *BMJ Qual Saf*, 21(1), 13–20.
- Ketelaar, N. A. B. M., Faber, M. J., Flottorp, S., Rygh, L. H., Deane, K. H. O., & Eccles, M. P. (2011). Public release of performance data in changing the behaviour of

- healthcare consumers, professionals or organisations. *The Cochrane Database of Systematic Reviews*, (11), CD004538.
- Kilsdonk, M. J., Siesling, S., Otter, R., & van Harten, W. H. (2016). Two decades of external peer review of cancer care in general hospitals; the Dutch experience. *Cancer Medicine*, 5(3), 478–485.
- Klazinga, N. S. (2000). Re-engineering trust: the adoption and adaption of four models for external quality assurance of health care services in western European health care systems. *International Journal for Quality in Health Care*, 12(3), 183–189.
- Kringos, D. S., Sunol, R., Wagner, C., Mannion, R., Michel, P., Klazinga, N. S., & Groene, O. (2015). The influence of context on the effectiveness of hospital quality improvement strategies: a review of systematic reviews. *BMC Health Services Research*, 15(1), 277.
- Lacey, A., & Luff, D. (2009). *Qualitative data analysis*. Nottingham: The NIHR Research Design Service for the East Midlands. The NIHR Research Design Service for Yorkshire and the Humber.
- Laverty, A. A., Smith, P. C., Pape, U. J., Mears, A., Wachter, R. M., & Millett, C. (2012). High-profile investigations into hospital safety problems in England did not prompt patients to switch providers. *Health Affairs*, 31(3), 593–601.
- Leatherman, S., & Sutherland, K. (2008). *The quest for quality: refining the NHS reforms. A policy analysis and chartbook*. London.
- Lewis-Parry, G. (2015). *Special measures*. Bangor: Betsi Cadwaladr University Health Board.
- Limb, M. (2012). Variations in collecting data on central line infections make comparison of hospitals impossible, say researchers. *BMJ*, 345, e6377.
- Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic Inquiry*. London: Sage Publications, Inc.
- Longley, M., Riley, N., Davies, P., & Hernández-Quevedo, C. (2012). *United Kingdom (Wales). Health system review. Health systems in transition* (Vol. 14). Copenhagen: European Observatory on Health Systems and Policies.
- Malley, J., Holder, J., Dodgson, R., & Booth, S. (2014). Regulating the quality and safety of long term care in England. In V. Mor, T. Leone, & A. Maresso (Eds.), *Regulating long term care quality - an international comparison* (pp. 180–210). Cambridge: Cambridge University Press.
- Manzano, A. (2016). The craft of interviewing in realist evaluation. *Evaluation*, 22(3) 342–360.
- Marks, R. (2014). *An independent review of the work of Healthcare Inspectorate Wales. The way ahead: to become an inspection and improvement body*. National Assembly for Wales, Health and Social Care Committee.
- Marshall, M., & McLoughlin, V. (2010). How do patients use information on health providers? *BMJ*, 341, c5272.
- Martin, J. (2008). Inspection of Education and Skills. In H. Davis & S. Martin (Eds.), *Public Services Inspection in the UK* (pp. 52–67). London: Jessica Kingsley Publishers.
- Martin, S. (2010). Knowledge from inspection: external oversight and information to improve performance. In K. Walshe, G. Harvey, & P. Jas (Eds.), *Connecting Knowledge and Performance in Public Services: From Knowing to Doing* (pp. 16–

- 32). Cambridge: Cambridge University Press.
- Mascini, P. (2013). Why was the enforcement pyramid so influential ? And what price was paid ? *Regulation and Governance*, 7, 48–60.
- Mcdermott, A. M., Hamel, L. M., Steel, D., Flood, P. C., & Mkee, L. (2015). Hybrid healthcare governance for improvement? Combining top-down and bottom-up approaches to public sector regulation. *Public Administration*, 93(2), 324–344.
- McGlynn, E. A. (2003). An evidence-based national quality measurement and reporting system. *Medical Care*, 41(1), 1-8-1-15.
- Mears, A. (2014). Gaming and targets in the English NHS. *Universal Journal of Management*, 2(7), 293–299.
- Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: an expanded sourcebook* (2nd ed.). London: Sage Publications, Inc.
- Nash, D. B., & Goldfarb, N. I. (2006). *The quality solution: the stakeholder's guide to improving health care*. London: Jones & Bartlett Learning.
- NHS Wales. (2014). *NHS Wales escalation and intervention arrangements*. Cardiff: Welsh Government.
- NHS Wales. (2015a). Betsi Cadwaladr University Health Board placed in special measures [online]. Retrieved March 3, 2016, from <http://www.wales.nhs.uk/news/37697>
- NHS Wales. (2015b). *Health and care standards*. Cardiff: Welsh Government.
- NHS Wales. (2016). Hospitals [online]. Retrieved February 8, 2016, from <http://www.wales.nhs.uk/ourservices/directory/hospitals>
- NHS Wales, & Welsh Government. (2014a). *Learning from Trusted to Care. Ministerial unannounced spot check visits. All Wales Report*. Cardiff: NHS Wales, Welsh Government.
- NHS Wales & Welsh Government. (2014b). *Learning from trusted to care. Ministerial unannounced spot check visits to Glan Clwyd Hospital, Bodelwyddan*. Cardiff: NHS Wales & Welsh Government.
- Nielsen, V. L., & Parker, C. (2009). Testing responsive regulation in regulatory enforcement. *Regulation and Governance*, 3, 376–399.
- Nuffield Trust. (2013). *Rating providers for quality: a policy worth pursuing ? A report for the Secretary of State for Health*. London: Nuffield Trust.
- Office of Public Services Reform. (2003). *Inspecting for improvement. Developing a customer focused approach*. London: Office of Public Services Reform.
- Øvretveit, J. (1997). A comparison of hospital quality programmes: lessons for other services. *International Journal of Service Industry Management*, 8(3), 220.
- Øvretveit, J. (2005). *What are the advantages and limitations of different quality and safety tools for health care?* Copenhagen: World Health Organisation.
- Øvretveit, J., & Gustafson, D. (2002). Evaluation of quality improvement programmes. *Quality and Safety in Health Care*, 11, 270–275.
- Patton, M. Q. (2002). *Qualitative research and evaluation methods* (3rd ed.). London: Sage Publications Ltd.
- Patton, M. Q. (2011). *Essentials of Utilization-Focused Evaluation*. Thousand Oaks:

Sage Publications, Inc.

- Pawson, R. (2002). Evidence-based policy: the promise of 'Realist Synthesis'. *Evaluation*, 8(3), 340–358.
- Pawson, R., Greenhalgh, T., Harvey, G., & Walshe, K. (2005). Realist review--a new method of systematic review designed for complex policy interventions. *Journal of Health Services Research & Policy*, 10 Suppl 1(July), 21–34.
- Pawson, R., & Tilley, N. (1997). *Realistic Evaluation*. London: Sage Publications Ltd.
- Population of Wales 2016 [online]. (2016). Retrieved April 9, 2017, from <http://ukpopulation2016.com/wales>
- Posavac, E. J. (2010). *Program evaluation: methods and case studies* (8th ed.). Boston: Pearson.
- Power, M. K. (1994). *The Audit Explosion*. London: Demos.
- Professional Standards Authority. (2015a). *Rethinking regulation*. London: Professional Standards Authority.
- Professional Standards Authority. (2015b). *Right-touch regulation. Revised*. London: Professional Standards Authority.
- Prosser, T. (2010). *The regulatory enterprise. Government, regulation, and legitimacy*. Oxford: Oxford University Press.
- Public Health Wales. (2014). Welsh Healthcare Associated Infection Programme [online]. Retrieved March 21, 2016, from <http://www.wales.nhs.uk/sites3/page.cfm?orgid=379&pid=51297> [Accessed March 21, 2016]
- Raleigh, V., & Foot, C. (2010). *Getting the measure of quality. Opportunities and challenges*. London: The King's Fund.
- Ritchie, J., & Spencer, L. (1994). Qualitative data analysis for applied policy research. In A. Bryman & R. G. Burgess (Eds.), *Analyzing qualitative data* (pp. 173–194). London: Routledge.
- Robson, C. (2011). *Real world research* (3rd ed.). Chichester: John Wiley & Sons.
- Rochira, S. (2013). *The work of the Healthcare Inspectorate Wales. Evidence from Older People's Commissioner for Wales - HIW 14*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- Rose, S. A. R. (2015). *Better leadership for tomorrow. NHS leadership review*. London.
- Rossmann, G. B., & Wilson, B. L. (1994). Numbers and words revisited: being "shamelessly eclectic"? *Quality & Quantity*, 28(3), 315–327.
- Royal College of Nursing. (2013). *The work of the Healthcare Inspectorate Wales. Evidence from the Royal College of Nursing - HIW 15*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- Sale, D. (2005). *Understanding clinical governance and quality assurance: making it happen*. Basingstoke: Palgrave Macmillan.
- Sale, J. E. M., & Brazil, K. (2002). Revisiting the quantitative-qualitative debate: implications for mixed-methods research. *Quality & Quantity*, 36, 43–53.
- Scrivens, E. (2007). The future of regulation and governance. *The Journal of the Royal Society for the Promotion of Health*, 127(2), 72–77.

- Selznick, P. (1985). Focussing organizational research on regulation. In R. G. Noll (Ed.), *Regulatory policy and social science* (pp. 363–367). London: University of California Press.
- Shadish, W. R. (1992). Theory-driven metaevaluation. In H. Chen & P. H. Rossi (Eds.), *Using theory to improve program and policy evaluations* (pp. 29–45). New York: Greenwood Press.
- Shaw, C. (2003a). *How can hospital performance be measured and monitored?* Copenhagen: World Health Organisation.
- Shaw, C. (2003b). Measuring against clinical standards. *Clinica Chimica Acta*, 333(2), 115–124.
- Shaw, C., & Kalo, J. (2002). *A background for national quality policies in health systems*. Geneva: World Health Organisation.
- Shekelle, P. G., Lim, Y.-W., Mattke, S., & Damberg, C. (2008). *Does public release of performance results improve quality of care? A systematic review*. The Health Foundation. London: Quest for Quality and Improved Performance, The Healthcare Foundation.
- Six, F. (2013). Trust in regulatory relations. *Public Management Review*, 15(2), 163–185.
- Smith, R. (1998). All changed, changed utterly. British medicine will be transformed by the Bristol case. *BMJ*, 316, 1917–1918.
- Spencer, L., Ritchie, J., & O'Connor, W. (2003). Analysis: practice, principles and processes. In J. Ritchie & J. Lewis (Eds.), *Qualitative research practice: a guide for social science students and researchers* (pp. 199–218). London: Sage Publications.
- Stame, N. (2004). Theory-based evaluation and types of complexity. *Evaluation*, 10(1), 58–76.
- Stigler, G. J. (1971). The theory of economic regulation. *The Bell Journal of Economics and Management Science*, 2(1), 3–21.
- Strategy Group Department of Health. (2012). *Performance and capability review of the Care Quality Commission*. London: Strategy Group, Policy Strategy and Finance, Department of Health.
- Sutherland, K., & Leatherman, S. (2006). *Regulation and quality improvement. A review of the evidence*. London: Quest for Quality and Improved Performance, The Healthcare Foundation.
- Taber, S. (2013). *Evidence from the Welsh Independent Healthcare Association - HIW 28. Response to the National Assembly for Wales' Health and Social Care Committee Inquiry into the work of Health Inspectorate Wales (HIW)*. London: National Assembly for Wales, Health and Social Care Committee.
- Talbot, C. (2010). *Theories of performance. Organizational and service improvement in the public domain*. Oxford: Oxford University Press.
- Thomas, A. (2013). *The work of the Healthcare Inspectorate Wales. Evidence from Hafal - HIW 08*. Cardiff: National Assembly for Wales, Health and Social Care Committee.
- Thomas, H. V. (2013). *The work of the Healthcare Inspectorate Wales. Evidence from the Auditor General for Wales - H 20*. Cardiff: National Assembly for Wales, Health and Social Care Committee.

- Thomson, R., Taber, S., Lally, J., & Kazandjian, V. (2004). UK Quality Indicator Project (UK QIP) and the UK independent health care sector: a new development. *International Journal for Quality in Health Care : Journal of the International Society for Quality in Health Care / ISQua*, 16 Suppl 1, i51-6.
- Tilley, N. (2009). Realistic evaluation and disciplinary knowledge: application from the field of criminology. In J. Vaessen & F. Leeuw (Eds.), *Mind the gap: perspectives on policy evaluation and the social science* (pp. 203–235). New Brunswick: Transaction Publishers.
- Tombs, S., & Whyte, D. (2013). Transcending the deregulation debate ? Regulation, risk, and the enforcement of health and safety law in the UK. *Regulation and Governance*, 7, 61–79.
- Torjesen, I. (2012). NHS has relied too heavily on regulation to improve quality of care, conference is told. *BMJ*, 345, e5968–e5968.
- Trochim, W. M. K. (1989). Outcome pattern matching and program theory. *Evaluation and Program Planning*, 12(4), 355–366.
- Tuijn, S. M., Robben, P. B. M., & Janssens, F. J. G. (2011). Evaluating instruments for regulation of health care in the Netherlands. *Journal of Evaluation in Clinical Practice*, 17, 411–419.
- Vaessen, J., & Leeuw, F. (2009a). Interventions as theories: closing the gap between evaluation and the disciplines. In J. Vaessen & F. Leeuw (Eds.), *Mind the gap: perspectives on policy evaluation and the social science* (pp. 141–170). New Brunswick: Transaction Publishers.
- Vaessen, J., & Leeuw, F. (Eds.). (2009b). *Mind the gap: perspectives on policy evaluation and the social sciences*. New Brunswick: Transaction Publishers.
- Veillard, J., Guisset, A.-L., & Garcia-Barbero, M. (2004). *Selection of indicators for hospital performance measurement. A report on the 3rd and 4th workshop. Barcelona, Spain, June and September 2003*. Copenhagen: World Health Organisation.
- Veloski, J., Boex, J. R., Grasberger, M. J., Evans, A., & Wolfson, D. B. (2006). Systematic review of the literature on assessment, feedback and physicians' clinical performance: BEME Guide no. 7. *Medical Teacher*, 28(2), 117–128.
- Vos, M. de, Graafmans, W., Kooistra, M., Meijboom, B., Voort, P. van der, & Westert, G. (2009). Using quality indicators to improve hospital care: a review of the literature. *International Journal for Quality in Health Care*, 21(2), 119–129.
- Wales Audit Office, & Healthcare Inspectorate Wales. (2013). *An overview of governance arrangements. Betsi Cadwaladr University Health Board*. Cardiff: Wales Audit Office, Healthcare Inspectorate Wales.
- Wales Audit Office, & Healthcare Inspectorate Wales. (2014). *An overview of governance arrangements. Betsi Cadwaladr University Health Board. A summary of progress against recommendations made in June 2013*. Cardiff: Wales Audit Office and Healthcare Inspectorate Wales.
- Walshe, K. (1999). Improvement through inspection ? The development of the new Commission for Health Improvement in England and Wales. *Quality in Health Care*, 8, 191–196.
- Walshe, K. (2003). *Regulating healthcare: a prescription for improvement?* Maidenhead: Open University Press.

- Walshe, K. (2007). Understanding what works-and why-in quality improvement: the need for theory-driven evaluation. *International Journal for Quality in Health Care*, 19(2), 57–9.
- Walshe, K. (2008). Regulation and inspection in health services. In H. Davis & S. Martin (Eds.), *Public services inspection in the UK* (pp. 68–86). London: Jessica Kingsley Publishers.
- Walshe, K. (2011). Managing performance. In K. Walshe & J. Smith (Eds.), *Healthcare management* (2nd ed., pp. 515–535). Maidenhead: Open University Press.
- Walshe, K., Addicott, R., Boyd, A., Robertson, R., & Ross, S. (2014). *Evaluating the Care Quality Commission's acute hospital regulatory model: final report*. London: The University of Manchester, Manchester Business School and The King's Fund.
- Walshe, K., & Boyd, A. (2007). *Designing regulation: a review*. Manchester: Centre for Public Policy and Management, Manchester Business School, University of Manchester.
- Walshe, K., & Phipps, D. (2013). *Developing a strategic framework to guide the Care Quality Commission's programme of evaluation*. Manchester: The University of Manchester, Manchester Business School.
- Walshe, K., Wallace, L., Freeman, T., Latham, L., & Spurgeon, P. (2001). The external review of quality improvement in health care organizations: a qualitative study. *International Journal for Quality in Health Care*, 13(5), 367–374.
- Weiss, C. H. (1998). *Evaluation: methods for studying programs and policies* (2nd ed.). Upper Saddle River: Prentice Hall.
- Welsh Assembly Government. (2003). *Fundamentals of care. Guidance for health and social care staff*. Cardiff: Welsh Assembly Government.
- Welsh Assembly Government. (2005a). *Concordat between bodies inspecting, regulating and auditing health and social care in Wales*. Cardiff: Welsh Assembly Government.
- Welsh Assembly Government. (2005b). *Healthcare standards for Wales. Making the connections. Designed for life*. Cardiff: Welsh Assembly Government, NHS Wales.
- Welsh Assembly Government. (2009). *Inspection, audit and regulation in Wales. Policy statement. Regulation*. Cardiff: Welsh Assembly Government.
- Welsh Assembly Government. (2010). *Doing well, doing better. Standards for health services in Wales*. Cardiff: NHS Wales, Welsh Assembly Government.
- Welsh Assembly Government. (2011). *National minimum standards for independent health care services in Wales*. Cardiff: Welsh Assembly Government.
- Welsh Assembly Government. (2014). Briefing. Review of the Standards for Health Services in Wales and Fundamentals of Care Standards [online]. Retrieved July 21, 2015, from <http://www.wcva.org.uk/what-we-do/policy-latest/2014/04/review-health-standards?src=newsletter>
- Welsh Government. (2014). Review of Standards for Health Services in Wales and Fundamentals of Care standards. Project team. Terms of reference [online]. Retrieved July 26, 2016, from https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiPs_Wk4bjVAhVILsAKHV5fAfgQFggtMAA&url=http%253A%252F%252Fwww2.nphs.wales.nhs.uk%253A8080%252FQuality%2526SafetyDocs.nsf%252Fcf3d6e123b990da080256fa300512475%252Fcd65952dc45b5b4580257d9e004901

- Welsh Government. (2016). Joint escalation and intervention arrangements [online]. Retrieved March 4, 2016, from <http://gov.wales/topics/health/nhswales/escalation/?lang=en>
- Welsh Government. (2017). Joint escalation and intervention arrangements [online]. Retrieved August 1, 2017, from <http://gov.wales/docs/dhss/publications/july-escalationen.pdf>
- Yin, R. K. (1992). The role of theory in doing case study research and evaluations. In H. Chen & P. H. Rossi (Eds.), *Using theory to improve program and policy evaluations* (pp. 97–113). New York: Greenwood Press.
- Yin, R. K. (2009). *Case study research: design and methods*. Los Angeles: Sage Publications, Inc.

9 Appendices

Appendix 1 Agreement between HIW and the researcher



Llywodraeth Cymru
Welsh Government

Terms of Agreement between Healthcare Inspectorate Wales and Anne Christine Hanser

This agreement sets out the areas of agreement relating to the University of Bath's participation, through PD student, Anne Christine Hanser.

Context

- Healthcare Inspectorate Wales (HIW) has agreed to provide some information and interviews with the student to support the completion of her PD

The Process

- The title of the PD thesis is 'Watchdogs for Healthcare - A comparative study of the Healthcare Inspectorate in Wales HIW and the Care Quality Commission CQC in England
- The primary purpose of the arrangement is for education and to further research by HIW and the student.
- The arrangement is not a contract of employment and does not create any legally enforceable rights or obligations.
- No party intends that this agreement is legally binding upon them nor does it create legally enforceable obligations on any party.

Costs and Contribution by ESRC and WG

- The student is not funded by HIW in any way. No reimbursement will be made for accommodation or travel costs or any other expenses or costs that may be incurred in connection with the PD.

Data Protection

HIW will comply with the Data Protection Act 1998 when processing personal data. The data will only be used for the administration of the project, statistical purposes and for the evaluation of their involvement. The data will not be used for any other purpose or shared with anyone outside of HIW.

Progress and Termination

- HIW may withdraw their participation in the PD during the period of this agreement if the student's work or conduct is unsatisfactory. Such withdrawal will not be made without prior consultation with the student and her supervisor.
- The process may be terminated if:
 - o HIW reasonably considers that the student is guilty of any gross or serious misconduct
 - o Any other party hereto commits a material breach of its obligations under this agreement

Conduct and Discipline

- It is a condition of the process that the student should ensure that there will be no conflict of interest that could damage the legitimate business interests of HIW or Welsh Government.

Official Secrets Acts, Confidentiality and access to government information

- Anne Christine Hanser shall keep secret and not disclose any information of a confidential nature obtained by the student by reason of the PD, except information that is in the public domain otherwise than for reason of a breach of this provision.
- A summary of the Official Secrets Act is attached (Annex A) for the attention of the student
- The obligation of confidentiality shall survive the termination of this agreement in perpetuity.

Informed Consent, Intellectual Property Rights and Publication

- It is advised that HIW staff have not, and will not provide informed consent to participate in any form of action research or participant observation research linked in any way to this PD unless explicitly agreed. The student is reminded of their ethical obligations in regard to this as set out in their professional code of practice. The student is also reminded that absence of informed consent precludes any production of case studies, vignettes, narratives or other publications on the work of government or government analysts, or the use of evidence in the policy process (including anonymised accounts) based on this period of evidence gathering.
- HIW are content that the ownership of the student's Intellectual Property Rights (with the exception stated below) has been assigned to the University of Bath by the student subject to its Intellectual Property policy. However, HIW reserves the opportunity to review the content within the PD about HIW.
- If the student wished to produce an academic journal article relating to the PD about HIW she should have formal agreement from the named HIW contact. The student should contact HIW if journal articles are produced when they are at final draft stage (before sign off) and HIW reserves the right to amend factual inaccuracies within the journal article and to publish a disclaimer as to views or conclusions expressed. The student should send in an electronic copy of the article at final draft stage and a page to view summary sheet (using the template dissemination briefing sheet – Annex C), and should allow 15 working days for a response from HIW.
- HIW encourages academic conference presentations but the student should seek written permission from the HIW contact if material about HIW is to be included. When a conference or other presentation is confirmed the student should provide HIW with information regarding the content/main focus of the presentation using the dissemination briefing sheet template (Annex C). At least

15 working days notice should be given to HIW before the date of the conference/presentation.

Press and Communication

Any press release or other communication with the media regarding this PD must be cleared with HIW press or communication teams. HIW require a minimum of 10 working days to comment on draft press releases or other media communications regarding the PD.

Agreement

The University of Bath is responsible for ensuring that Anne Christine Hanser is aware and follows the terms of this Agreement.

Please confirm that you are prepared to accept the basis of this Agreement by signing and returning a copy to your named contact above.

Signed on behalf of Healthcare Inspectorate Wales



15/07/14

Date:.....

Signed on behalf of the University of Bath:.....



Date: 2/6/14

I acknowledge that I have read and understood and will abide by the terms and conditions of this Agreement.

Signed by Anne Christine Hanser:.....



Attachments:

Annex A: Summary of the Official Secrets Act

Annex B: HIW dissemination briefing template



OFFICIAL SECRETS ACT 1989

1. The Official Secrets Act 1989 came into force on 1 March 1990. The 1989 Act replaces section 2 of the Official Secrets Act 1911, under which it was a criminal offence for a civil servant to disclose any official information without lawful authority. Under the 1989 Act it is an offence to disclose information only in one of six specified categories and, in general, only if the disclosure can be shown to have damaged the national interest in a specified way.

These paragraphs are not comprehensive; more detailed advice or guidance about the Act may be obtained from Employment Policy Team, Personnel Division.

Application of the Act

2. The Act applies to:
 - Crown servants
 - Government Contractors, including anyone employed in the provision of goods or services for the purposes of a Minister
 - Small number of office holders and staff of a small number of non-government organisations
 - Members of the public who have, or have had, official information in their possession

"Official information"

3. In the following paragraphs, the word "information" refers to any information, document or article which a crown servant or government contractor has or has had in their possession by virtue of his or her position as such.

"Without lawful authority"

4. An offence is committed under the Act if and only if the information disclosed by a civil servant is disclosed without lawful authority. Information is disclosed with lawful authority if it is disclosed in accordance with the crown servant's official duty. Government contractors may do so only in accordance with an official authorisation or for the purposes of their function as contractors.

The 6 protected categories

5. Information is protected by the Act if and only if it is in one of the following six categories:
 - Security & Intelligence
 - Defence
 - International relations
 - Foreign confidences
 - Information which might lead to the commission of crime
 - The special investigation powers under the Interception of Communications Act 1985 and the Security Services Act 1989

When is disclosure damaging?

6. The act sets different tests of damage for each of the 6 categories of information. For an

offence to be committed under the Act, the disclosure of information must in general have damaged the national interest in the particular way, or ways specified in the Act for the category of official information in question. It is ultimately for the court to decide, when the case comes to trial, whether the damage has in fact occurred.

The security and intelligence services

7. A person who:
- is or has been a member of the security and intelligence services; or
 - has been notified in writing that he or she is subject to section 1(1) of the Act

It is an offence to disclose without lawful authority any official information about security or intelligence. There is no damage test.

Safeguarding of information

8. It is also an offence under the act:
- for a crown servant, a government contractor or a notified person to fail to take reasonable care to prevent the unauthorised disclosure of a document or article which is protected by the Act
 - for a crown servant or notified person to retain such a document or article contrary to official duty
 - for a government contractor or a member of the public to fail to comply with an official direction for the return or disposal of such a document or article
 - if information is disclosed which can be used for the purpose of obtaining access to information in one of the specified categories and the circumstances in which it is disclosed are such that it would be reasonable to expect that it might be used for that purpose without authority

Penalties

9. The offences described in the previous paragraphs, except the offences described in paragraph 8, may be tried either on indictment, by the Crown Court, or summarily, by a magistrates' court. The maximum penalties are two years' imprisonment or an unlimited fine, or both, if the offence is tried on indictment, and six months' imprisonment or a £2,000 fine, or both, if the offence is tried summarily. The offences described in paragraph 8 above are summary offences, triable in England and Wales by a magistrate's court. The maximum penalties are 3 months' imprisonment or a £2,000 fine or both.

Section 1 of the Official Secrets Act 1911

10. The 1989 Act does not affect the operation of section 1 of the Official Secrets Act 1911, which protects information useful to an enemy. The maximum penalty for offences under section 1 of the 1911 Act is 14 years' imprisonment.

I have read and understood this document:

Signed: _____

Name: Anne Christine Hanser

Date: _____

03.05.2014

Dissemination Briefing Sheet A:

Academic Journal Publication relating to PD

It is anticipated that you will have already discussed this article with your Supervisor. Therefore, please contact HIW when journal articles are at final draft stage (before sign off of the final draft) and please allow **15 working days** for a response.

Title of Journal article

Title of Journal

Anticipated Date of Publication (month/edition)

Journal Article Abstract

Please attach the full final draft of your article in electronic format. You may wish to note that the article will be viewed as research in confidence and draft by HIW and will not be circulated outside of HIW.

Please email the draft article and this form to ruth.studleyl@wales.gsi.gov.uk

Dissemination Briefing Sheet B:**Conference or Seminar Presentation relating to your PD**

It is anticipated that you will have already discussed this presentation with your Internship Supervisor. Therefore, please provide HIW with a minimum of **15 working days** notice of your presentation.

Title of Presentation**Title of Conference or Seminar Series****Date of Presentation****Anticipated Presentation Content Themes**

It is appreciated that preparation may continue up to the day before the conference or seminar. If three to four weeks ahead of the presentation your development is at an early stage, please provide an abstract and/or four or five bullet points on the main themes/focus of your presentation. If you are able to provide more information nearer to the presentation date that would be helpful, though not essential.

You may wish to note that any information will be viewed in confidence by HIW and will not be circulated outside of HIW.

Please email the draft article and this form to ruth.studley@wales.gsi.gov.uk

PARTICIPANT INFORMATION SHEET (HOSPITAL)

Watchdogs for Healthcare - a comparative study of the Healthcare Inspectorate in Wales (HIW) and the Care Quality Commission (CQC) in England

This evaluation study is being conducted by Ms Anne – Christine Hanser, as part of her professional doctorate studies in health at the University of Bath, and supervised by Dr Louise Brown. Their contact details are provided at the bottom of the information sheet.

The purpose of the study is to determine the strengths and weaknesses of the different regulation and inspection regimes being applied in acute care hospitals in England and Wales.

The study will analyse and compare the differences in design and implementation of the inspectorate model in Wales and England. The views and evidence that you and other interviewees provide may help us to better understand the mechanisms that make hospital inspections work (or not) in their particular context. We will forward our findings including the suggestions for changes, which the study participants express, to the HIW and CQC for their consideration.

You and the organisation you work at are being asked to take part in this study due to your previous experience with, involvement in or managerial responsibility for hospital inspections and spot-checks conducted by the HIW, CQC or the Welsh government. The participation is entirely voluntary, i.e. you can freely choose whether or not to participate. If agree to participate, but wish to withdraw from the study at a later stage, you just need to inform the evaluators of your decision. You can withdraw from the study at any time without penalty.

Your participation in the study would entail:

- Arranging an appointment for an interview at a time and place convenient to you.
- Answering questions and sharing your views in a face-to-face interview with the evaluator. This will take approximately 45 – 60 minutes. The conversation will be audio-recorded during the interview and transcribed (written down) afterwards. The information that you share with the evaluator will be kept confidentially. This means that your name/identity will not be disclosed in the evaluation report, unless you explicitly wish this. The personal data will be stored in a safe, which only the evaluators will have access to. The interview tape and text will be destroyed after the evaluation will be completed.
- Possibly, you will be asked at a later stage to (i) clarify particular questions or (ii) give feedback on how the evaluator interpreted the interview(s). The clarifications and feedback would normally be exchanged via email (or telephone).

If you wish,

- you will receive an electronic and/or hardcopy of the interview text, the major findings (summary) and/or the entire evaluation report.

This project has been reviewed by and received ethics clearance through the Research Ethics Approval Committee for Health of Bath University. The study is not expected to impose any elevated risks to the participants. There are no direct benefits for the participants involved. We hope however that the study may have a positive, but indirect impact through the publication of its findings.

Please take your time to make your decision about whether you would like to be in this study. Please ask any questions that you might have before you decide.

Our contact information:

Evaluator:

Anne Christine Hanser, professional doctorate student

Email: [REDACTED]

telephone: +44-[REDACTED] (landline), +44-[REDACTED] (mobile)

Academic supervisor:

Dr Louise Brown, reader at the Department of Social and Policy Sciences

Email: l.brown@bath.ac.uk

telephone: +44-1225-385284

CONSENT FORM

The title of the study:

Watchdogs for Healthcare - a comparative study of the Healthcare Inspectorate in Wales (HIW) and the Care Quality Commission (CQC) in England

The name and status of the evaluators:

Chief investigator:

Dr Louise Brown, reader at the Department of Social and Policy Sciences
Email: l.brown@bath.ac.uk
telephone: +44-1225-385284

Other investigator:

Anne Christine Hanser, professional doctorate student
Email: [REDACTED]
telephone: +44-[REDACTED] (landline), +44-[REDACTED] (mobile)

The purpose of the study:

To determine the strengths and weaknesses of the different regulation and inspection regimes being applied in acute care hospitals in England and Wales.

Declaration

As a participant in the above evaluation study, I declare that I

- have read the participant information sheet ☐
- have had the opportunity to ask questions about the study and have received satisfactory answers to questions and any additional details requested ☐
- understand that I may withdraw from the study without penalty at any time by advising the evaluators of this decision ☐
- understand that this project has been reviewed by, and received ethics clearance through, the Research Ethics Approval Committee for Health of the University of Bath ☐
- understand who will have access to personal data provided, how the data will be stored, and what will happen to the data at the end of the project ☐
- agree to participate in the study ☐

Participant:

(Signature)

Evaluator: Anne Christine Hanser

(Signature)

Appendix 4 Interview guides

Appendix 4.1 Initial interview guide – for piloting

Interview topic guide for semi-structured-interviews on inspections amongst

- **Hospital managers**
- **HIW managers and inspectors**
- **Healthcare policy and decision makers**
- **Independent experts**

Note:

Each interview is expected to last between 45 and 60 minutes. Due to the limitation in time and the specific profiles of the different informant groups, it will not be possible to cover all research topics in each interview. I will focus on the topic that is most relevant for the respective interviewee (category). Yet, all topics will be covered across the interviews. The following interview guide is a draft version, which will be refined in the document review/analysis (stage 1 of the PD-study) and the subsequent piloting.

1 Introduction - approx. 5 minutes

- *Thank interviewee for participating in the study.*
- *Introduce myself, interview will last approx. 45 – 60 minutes*
- *Explain the purpose of the study: to determine the strengths and weaknesses of the inspectorate model comparing the HIW (Wales) and CQC (England).*
- *Reassure re: written informed consent, confidentiality – the study report will not reveal names of informants and hospital sites, therefore nothing you say will be linked to your identity,*
- *Asking for permission for audio-recording.*
- *Explain importance of interviewee expressing his/her views. All opinions will be valid and helpful.*
- *Check interviewee is comfortable with setting, expected duration, interview format and subject matter.*
- *The interviewee may ask questions her/himself at any time during the interview, especially when clarification is needed.*

2 Informant Introduction - 5 minutes

- *Could you please introduce yourself (Interviewer: make sure that name, age, position corresponds and contact details, including email-address correct)*
- *Your current position in the hospital [or inspecting body, or other organisation] and role in quality management etc.*
- *Your involvement in inspections in THIS hospital [or inspecting body or other organisation etc.] - including when, how many, which kind of inspections, HIW or CQC*
- *Have you been involved in other inspections outside THIS hospital [or inspecting body, organisation etc.], e.g. same or similar role as in this hospital [or inspecting body, administration etc.], or a peer reviewer/inspector [hospital staff/manager etc.]*
- *Interviewer: exploring the respondents' role and experience with hospital inspections will help identifying relevant topics to further discuss. Check interviewee's body language for any signs of discomfort.*

3 Research topics - 30 - 45 minutes

- *Interviewer: Make notes during the interview, i.e. important statements, emphasises, body language.*

Current inspection regime

- I would like to ask about your experience with hospital inspections.
- Please describe the last hospital inspection you were involved in / responsible.
(Probe – current inspection regime)

Further, more specific questions: **[for key informants from hospitals]**

- What information did you receive about the HIW/CQC's inspection prior to their visit to the hospital? (announced/unannounced, time in advance) How long did the inspection last?
- Which wards in the hospital were visited? What was the (thematic) focus?
- Who were the inspectors (team, qualification)? Profession of the counterparts at the hospital? How did both work together?
- What was your specific role? How did the inspection affect your and your colleagues' work? And the ward / hospital as a whole? (any positive or negative changes) For example: preparation before, cooperation during, and tasks to do after the inspection.

General views and functioning mechanisms

- What was your general impression of the inspection? Alternative: How do you judge inspections from your professional point of view?

Further, more specific questions:

- What effects have the following elements of the inspection regime had (in THIS hospital, if not THIS hospital – please specify which hospital)?
 - Set of (national) health quality standards for acute care hospitals (to be inspected against) have been developed in a transparent and professional way (- did this happen and if what effects)?
 - The national health quality standards for acute care hospitals have been set in a way that makes it very easy for the majority of hospitals to reach them (- did this happen and if what effects)?
 - The national health quality standards for acute care hospitals are balanced and reflect all relevant performance areas (- did this happen and if what effects)?
 - Inspection / quality standards are being communicated by HIW/CQC (other third parties) to the hospital well in advance (- did this happen and if what effects)?
 - HIW/CQC (or other third parties) provide sufficient and useful guidance in advance to the hospital about how to operationalise inspection / quality standards in the hospital (- did this happen and if what effects)?
 - HIW/CQC informing the hospital in advance about an upcoming inspection (- did this happen and if what effects)?
 - HIW/CQC unexpectedly arriving at the hospital and conducting an unexpected inspection (- did this happen and if what effects)?

- HIW/CQC inspectors identifying the critical issues / problems at the hospital during the inspections? (- did this happen and if what effects)?
- HIW/CQC inspectors assessing the hospital's performance adequately during the inspections? (- did this happen and if what effects)?
- HIW/CQC inspectors giving valuable advice & practical recommendations for improvements during the inspections (- did this happen and if what effects)?
- HIW/CQC inspectors giving valuable advice & practical recommendations for improvements after the inspections (- did this happen and if what effects)?
- HIW/CQC discussing and agreeing with the hospital on appropriate actions for improvements (- did this happen and if what effects)?
- HIW/CQC submitting reports to the hospital for commenting before publishing (- did this happen and if what effects)?
- HIW/CQC publishing inspection reports (with their negative assessment) on their website (- did this happen and if what effects)?
- HIW/CQC publishing inspection reports (with their positive assessment) on their website (- did this happen and if what effects)?
- HIW/CQC (or other organisation) reviewing the progress made after the last inspection / implementation of the agreed or imposed changes? (- did this happen and if what effects)?
- HIW/CQC or other organisation conducting other activities to enforce compliance with standards / improve performance? (- did this happen and if what effects)?
- Population, media, other hospitals, NHS, or other organisations or individual (please specify) have expressed positive or negative feedback after the publication (- did this happen and if what effects)?
- Patient have been more reluctant to use the hospital after he publication of a negative assessment (- did this happen and if what effects)?
- Patient numbers (or similar) increased after the publication of a positive assessment (- did this happen and if what effects)?
 - Have you identified any other elements of the inspections or positive or negative effects that you associate with the hospital inspection?
- What specific advantages does the current inspection regime have?
 - Versus previous regimes (or regimes other inspectorates employ)
 - Vs. alternative solutions like voluntary peer review or self-assessment as applied in accreditation, supervisory audits and commands in hierarchical supervision or market competition etc.
 - Vs. complete freedom
- From your point of view, what are the major strengths of hospital inspections? (*for key informants from hospital: at THIS hospital and acute care hospitals in general*)
- What are the major weaknesses of inspection from your point of view? What specific disadvantages does the current inspection regime have? Alternative: What negative 'side-effects', if any, have you observed within the hospital (or outside) since the introduction of hospital inspections?
- From your point of view, what is the major purpose that hospital inspections seek to fulfil? (quality assurance, quality improvement, accountability)

- How far do you think does the current inspection regime achieve these objectives? (e.g. scale between 0 – 10)

Development of inspection models/regimes

- What changes did you experience concerning inspection models and regimes and their implementation at the hospital(s) over the last few years?
- ((What triggered those changes from your point of view? *Alternative:* What factors or conditions do you think have led to the changes?))
- How did the hospital (i.e. hospital managers and staff) receive those changes?
(*Note: it might be necessary to address each change separately*)
- How did you regard these changes that time and how do you consider them now retrospectively?

Proposed changes

- If you were in power to design and implement a system that that addressed these objectives (quality assurance, quality improvement, accountability), what would be its major components?
- If your task was to adopt the current inspection model/regime, which changes would you suggest?

4 Wrapping up - 5 minutes

- What do you consider the most important things that we've spoken about?
- Is there anything else that you'd like to raise?
- Any questions?
- Informing about further proceedings: sending the typed interview-text, possibility of clarification, opportunity to give feedback on draft research report
- Snowballing: it will be crucial for this study to interview more people (also those with possibly different views) from this organisation / hospital or other relevant organisations / hospitals. Could you please forward my contact details to such people or share addresses of people with me that you think might be interested in being interviewed.
- Thank and close

Further topics for the interviews with key informants from CQC&HIW, governmental bodies, independent experts

Context & Cooperation

- What motivated the establishment of CQC/HIW from your point of view? What have been the driving factors?
- Who 'benefits' (most) from the work of CQC/HIW? (government, the public, the patients, the hospitals, the staff, the NHS et al.)
- What is the relation between CQC and HIW?
- What is the relation between CQC/HIW and other governmental or non-governmental institutions that have similar objectives?

- What do you consider as the major differences between the CQC and HIW – and the setting the work in?
- How far have CQC and HIW learnt from each other? (or other institutions)

HIW and CQC as institutions

- What are the characteristics of the two institutions:
 - Structure, profile, number of staff, budget, no. of health services to oversee
 - How independent are CQC/HIW? (funding, decision-making and reporting)
 - What are the mechanisms to assess the performance of CQC/HIW? (external/internal, frequency, etc.)
- What are their roles and their self-perception?
 - mandates & objectives?
 - How far were the 'traditions' of predecessor organizations incorporated?
 - What contributions did CQC/HIW make to public debate, agenda setting and policy setting related to quality improvement?
- What is the underlying philosophy / regulatory model?
- What strategy do they follow with regard to direction, detection and enforcement?
- What is the actual focus of activities?

Organisational development and Lessons learnt

- What changes has CQC/HIW undergone since its establishment? (structural, processual etc.)
- What motivated those changes? (factors, incidents, change in government etc.)
- What (strategic/future) changes are envisaged? And why?
- What (else) can be learnt from the experience so far?

Inspection model and regime

- How is the inspection (=external assessment) process currently organized?

Further, more specific questions:

 - Different types of inspections
 - Strategy (focus on qualitative, quantitative, mixed methodology)
 - Specific methods in combination with inspections, like audits, surveys etc.
 - Sources of information
 - Tools
 - Composition of teams
 - Status & qualification: (full-/part-time) staff or free-lance consultants, professionals, high-profile experts?
 - Consistency: measures to prevent or reduce bias
 - Transparency: Inspection results (why published), CQC (why was the star-rating system abandoned)
- To what extent have the inspection models been adapted and developed over time?
- What specific barriers have been encountered in the implementation?
- Which positive or negative changes have you observed within acute-care hospitals that can be associated with the inspections of CQC/HIW?

Interview topic guide for interviews on inspections (hospital managers)

1 Introduction - approx. 5 minutes

- *Thank you for participating in the study (+ hand over business card)*
- *How much time do you have available? - Typically, an interview lasts approx. 60 minutes.*
- *While the purpose of the study is to determine and compare the strengths and weaknesses of the inspection regimes applied by the HIW (Wales) and CQC (England) – naturally, this interview will focus on HIW as your hospital is being regulated by HIW. However, if you have first-hand experience with CQC inspections, feel free to mention those explicitly during the interview.*
- *(hand over written informed consent and information sheet) – the study report will not reveal names of informants and hospital sites, the transcripts will not be enclosed in the final report, therefore nothing you say will be linked to your identity. Please find more information on the information sheet and the consent form. [Allowing time for the participant to read the information form and the consent form.] As you can see there, the participation in this research is voluntary and you can withdraw from the study at any time. [clarifying any questions or concerns] – If you agree on participating in the study, please sign here the consent form. One copy will remain with you, one I will take with me.*
- *With your permission I would like to audio-record the interview.*
- *Feel free to ask any questions yourself at any time during the interview, especially when clarification is needed.*

2 Informant Introduction - 5 minutes

- *Could you please briefly introduce yourself (such as your name, your role in the organisation, professional background)*
- *What has been your involvement in inspections in this hospital - including when, how many, which kind of inspections?*
- *Have you been involved in other inspections outside this hospital, e.g. similar role as in this hospital or as a peer reviewer?*

3 - Research topics - 30 - 45 minutes

Current inspection regime

I would like to ask you about your experience with hospital inspections:

- *Could you please describe the **last** hospital inspection you were involved in or responsible for.*

Further, more specific questions:

- *When was the last inspection?*
- *What information did you receive about the HIW inspection prior to their visit to the hospital?*
- *If it was announced, how much time in advance?*
- *How long did the inspection last?*
- *What type of inspection was it? (i.e. a general / revalidation / follow-up / (thematic) focus?*

- Which wards in the hospital were visited?
- Who were the inspectors, i.e. what was their professional profile/qualification?
- Who were the counterparts in the hospital? i.e. Whom did they meet and interview?
- How did the cooperation between the inspectors and the hospital staff / managers proceed?
- What was your particular role in the inspection?
- What was your general impression of the (last) inspection?

Functioning mechanisms

As part of the methodology I am employing in this research, I am looking at specific elements of the hospital inspections. The aim is to find out what works in which particular setting – or what does not work there. I am going to ask you about your experience with the particular elements of the inspection regime (in THIS hospital, if not THIS hospital – please specify which hospital).

Quality standards

- What is your experience with the **quality standards** for acute care hospitals which HIW employs for the inspections?

Further, more specific questions:

- What is your professional opinion about these standards?
- What is your judgement concerning the achievability of the standards for acute care hospitals? -> What factors make them more or less achievable for a hospital?
- How have they been communicated to the hospital?
- How were they operationalised in the hospital?
- What specific effects did the application of these **standards** during the inspections have?

Self-assessments *(relevant for members of Local Health Boards)*

- What is your experience with the **self-assessments** which the board submits to HIW?

Further, more specific questions:

- What are the advantages?
- What are the disadvantages?
- What specific effect do they have?
- Which conditions increase the effectiveness of these self-assessments?

Type of inspections

- What is your experience with announced HIW inspections?

Further, more specific questions:

- What were the advantages?
- What were disadvantages?

- What specific effect did the announced HIW inspections have?
- Which conditions increase the effectiveness of announced inspections?
- What is your experience with **unannounced** HIW inspections?

Further, more specific questions:

- What were the advantages?
- What were disadvantages?
- What specific effect did the **unannounced** HIW inspections have?
- Which conditions increase the effectiveness of unannounced inspections?
- What is your experience with **general** HIW inspections?

Further, more specific questions:

- What were the advantages?
- What were disadvantages?
- What specific effect did the **general** HIW inspections have?
- Which conditions increase the effectiveness of general inspections?
- What is your experience with themed HIW inspections?
- Further, more specific questions:
 - What were the advantages?
 - What were disadvantages?
 - What specific effect did the **themed** HIW inspections have?
 - Which conditions increase the effectiveness of themed inspections?

Inspection teams

- What is your experience concerning the **inspection teams**?

Further, more specific questions:

In particular, (what is your experience concerning)

- their ability to identify critical issues at the hospital during the inspections?
- their ability to assess the hospital's performance adequately?
- Which characteristics and conditions increase the effectiveness of the inspection teams?

Advice and Recommendations / Inspection report / enforcement / follow-up

- What is your experience concerning the **advice & recommendations** for improvements that were given during or after the inspections?

Further, more specific questions:

- What is your experience concerning actions for improvements?
- Which conditions increase the effectiveness of the recommendations provided by HIW?

- What is your experience with **inspection reports**?

Further, more specific questions:

- What is your experience with reports submitted to the hospital for commenting before publishing?
- What effect / impact did they have?
- What effects did inspection reports with positive assessment results have?
- (Please provide concrete examples. Did the population, media, other hospitals, NHS, or other organisations or individual express feedback after the publication? Did patient numbers increase or decrease? Did staff morale rise or fall?)
- What effects did inspection reports with negative assessment (if there were any) results have?
- Which (other) conditions increase the effectiveness of the inspection reports?
- How far are you aware of **inspection results of other** health boards or competitive hospitals?
- That is your experience with **follow-up or review procedures** after an inspection (if there were any)? (for example, to ensure the implementation of agreed or imposed actions)

Further, more specific questions:

- (if applicable:)What is your experience with HIW or other organisations conducting other activities to enforce compliance with standards / improve performance?
- What effects did the particular measures have?

Other elements?

- Have you identified any other elements of the inspections or positive or negative effects that you associate with the hospital inspection? (if yes, which?)

The interviewee's professional judgement /evaluation of inspections

- How overall do you judge inspections in general from your professional point of view?
- From your point of view, what are the major **strengths** of the hospital inspections that HIW conducts?

Further, more specific questions:

- What specific advantages does the current inspection regime have?
 - Versus previous regimes (or regimes other inspectorate employ)
 - Vs. alternative solutions like voluntary peer review or self-assessment as applied in accreditation, supervisory audits and commands in hierarchical supervision or market competition etc.
 - Vs. complete freedom
- What are the major **weaknesses** of HIW's hospital inspections from your point of view?

Further, more specific questions:

- What specific disadvantages does the current inspection regime have?
Alternative: What negative 'side-effects', if any, have you observed within the hospital (or outside) since the introduction of hospital inspections?
- From your point of view, what is the **major purpose** that HIW's hospital inspections seek to fulfil? (quality assurance, quality improvement, accountability)

Further, more specific questions:

- How far do you think does HIW's current inspection regime achieve these objectives? (e.g. scale between 0 – 10)

Proposed changes

- If you were in power to design and implement a system that that addressed these objectives [-> objectives stated in research literature: quality assurance, quality improvement, accountability, informing the government], what would be its major components?
- If your task was to adopt HIW's current inspection regime, which changes would you suggest?

4 Wrapping up - 5 minutes

- What do you consider the most important things that we've spoken about?
- Is there anything else that you'd like to raise?
- Any questions?
- [Informing about further proceedings]: I will send you the typed interview-text within the next few weeks. Feel free to clarify or add comments. Moreover, if you have time, it would be very nice if you could provide feedback on draft research report, which contains the analysis and conclusions of all interviews and research materials.
- [Snowballing]: it will be crucial for this study to interview more people - also those with possibly different views - from this hospital or other relevant hospitals or organisations. Could you please share addresses of people with me that you think might be interested in being interviewed. Or forward my contact details to them.
- Thank you very much for the interview and your support! (handing over ...)

Interview topic guide for semi-structured-interviews on inspections with HIW managers

1 Introduction - 5 minutes

(a) the study

- **Thank you** for participating in the study (+ hand over business card)
- How much **time** do you have available?
- The **purpose** of the study I have explained during the presentation. While today's interviews naturally focus on HIW inspections. However, you may wish to refer also to CQC inspection regimes. In those cases, please explicitly mention the CQC - in order for me not to confuse between the two.
- (Reassure re: written informed consent, **confidentiality**) – the study report will not reveal names of informants and hospital sites, the transcripts will not be included in the final report, therefore nothing you say will be linked to your identity.
- With your permission I would like to **audio-record** the interview.
- Feel free to **ask any questions** yourself at any time during the interview, especially when clarification is needed.

(b) the informant

Usually, I ask the interviewee at the beginning to introduce herself, such as professional background and experience, anything that you consider important for the context of the interview.

2 The mechanisms - 40 –50 minutes

Functioning mechanisms (can skip this part, if the presentation has made that clear already)

In my thesis, I am pursuing a **realist-based programme evaluation** methodology, which aims to **first** identify the **mechanisms** that are *supposed* to make a policy or programme or in our case the inspection regimes (for acute care/general hospitals) effective. In a **second step**, I am trying to find out in how far the regimes have been implemented the way they were supposed to and **thirdly** which of the *particular elements* of the inspection regimes have achieved their purpose in which particular hospital setting or **context**. (I.e. to find out what works in which setting and what does not). Your contribution to this study will be especially valuable given your profound, inside experience at HIW and your recent experience – working on the other side ..., the hospitals.

I have prepared **schematic charts in table-form** for some (but not all) elements of the inspection regimes and would like to go with you through them. Thereby, it would be good if you could comment on

- the positive effects (or negative side effects) of the particular elements according to your experience and
- whether the elements were relevant for the inspections in Wales and
- Possibly whether you experienced any differences in the effectiveness of those elements depending on the specific setting, for example whether it was an NHS or independent sector hospital.

2.1 Registration

My understanding is that only independent sector hospital service providers have to register – not the NHS hospitals.

- What is the purpose of the registration required for hospital service providers?
 - Threshold to meet for performance – i.e. deter potential service providers who are unfit?
 - Relationship building with provider - i.e. establish an intensive relation, advice /direct the new service provider etc.?
 - Administrative data capture – get as much data as possible about the new service provider?
- Why do NHS hospitals not have to register? – What is the rationale behind?
- How often does a new service provider appear and thus has to register?
- What happens in the case that a hospital is sold to another service provider?
 - One interviewee described a 'light' inspection... is this the norm?
- How successful has HIW in achieving the above-mentioned purpose?

2.2 Standards

According to research literature, standards play an important part in the regulatory process, particularly for providing 'direction' to the regulated organisations.

My understanding is that there are 26 healthcare standards in Wales for NHS hospitals, revised in 2010 and published as 'Doing well, doing better'. One interviewee said however, that those standards apply to both, the NHS and independent sector healthcare providers. There are, however, the 25 'national minimum standards for independent health care services in Wales', revised in 2011. I do understand that the two sets of standards are consistent and do not contradict each other –

- I just want to clarify whether or not formally the 'Doing well, doing better standards' also apply to the independent sector, was one interviewee said.
- And why would you not have ONE integrated set of standards, which may in one or another point differentiate between independent and NHS hospitals?
- And why are the standards currently reviewed again – although the last revision is only 3 or 4 years ago. It does not seem plausible to me that rather generic standards in healthcare would change within such a short period of time?
- What is the major purpose of the two sets of standards?
 - Framing values and expectations – rather than being concrete and precise. (*Standards are an explicit expression of values more than they are a tool for performance measurement.*) By the size of the documents, it seems to me that the minimum standards for the independent sector are given more explicit guidance than the NHS standards – correct?
 - Improvement through self-enforced compliance (*'So these standards are likely to be maximal, explicit, detailed, and accompanied by further guidance'*)
 - Compliance through measurement and enforcement – relatively easy to reach (*since the regulator is unlikely to be able to take enforcement action with more than a small proportion of providers*)

- Differentiating performance of providers – ‘a wide variation of performance levels’. – I don’t see this at all in Wales at the moment.
- According to your experience, what are the **particular mechanisms** that make standards work (well) in hospital inspections?

Possibly, check the following scheme with the interviewee

Regulator	Regulated hospital	Possible output/outcomes
Develops and promulgates standards or requirements	1. Learns about standards / requirements	<u>Short-term</u>
	2. Considers them appropriate and feasible	• hospital managers/staff informed about standards
		• changes planned and implemented
		• compliance increased
		• performance improved in required areas
Provides guidance and advisory information on how to ...	3. Identifies the resulting need for changes and plans accordingly	<u>Negative:</u>
	4. Implements changes	• non-compliance issues remain (partly)
		• performance not improved in other areas

- Which **contextual factors increase** the effectiveness of regulatory standards according to your experience?
- Which contextual factors **reduce** the effectiveness of standards?

Further, more detailed questions:

CQC discussed and developed the requirements for their inspections in a participative process that took several months and included a number of working meetings with the major stakeholders across England.

- What degree of **involvement** should stakeholders have in the development of standards to make the standards an effective element in the regulation mechanisms?
- What degree of **achievability** should standards have to make them an effective element in the regulation mechanisms?
- How should standards be **communicated** to make them an effective element in the regulation mechanisms?
- In how far do you consider does HIW achieve this purpose by applying the standards in their hospital inspections? Or:
- What is your experience with the effectiveness of the **standards that the HIW** applied in their inspections hospitals in Wales? This question relates to the actual implementation of hospital inspections by HIW.

Further, more detailed questions:

- What **differences**, if any, in the effectiveness of standards have you experienced concerning NHS and independent sector hospital inspections?
- What **changes**, if any, would you suggest concerning the standards that the HIW applies for hospital inspections? (ie. which aspects could still be improved by HIW, which are already perfectly suiting?)

2.2 Prior risk assessment and data analysis




According to the concept of risk-based (or proportionate regulation), the regulatory ability to gather and analyse relevant hospital data plays an important role in the 'detection' of hospitals that present a potentially larger threat to patients.

- What is in your opinion the **major purpose** of HIW analysing and assessing the risks of particular hospitals?
 - Driver for improvement in advance of inspection
 - Determining when to use regulatory interventions
 - Focusing or directing attention during regulatory intervention
 - Making providers aware that regulator may intervene

My understanding is that HIW conducts hospital inspections regularly / anyway (at least for the independent sector hospitals), i.e. does not chose particular hospitals.

- What about NHS hospitals – are the validations of self-assessments made on a yearly basis or depending on the risk assessment? Or do the data provided in the self-assessments form one part of the risk assessments?
- How would you distinguish between the various hospitals within a health board? Would you pick one hospital that has particular health data? Or choose more hospitals from a health board with poor results?
- According to your experience, what are the **particular mechanisms** that make prior risk assessment and data analysis work effectively?

Possibly, check the following scheme with the interviewee

Regulator	Regulated hospital	Possible output/outcomes
1. Aggregates relevant, reliable and up-to-date information / intelligence about the hospital from various sources;  2. analyses the data appropriately, and  3. selects the hospital and/or the inspection regime accordingly	1. Regularly assesses its own performance level and risks (against the regulatory requirements)  2. Acts appropriately upon risks and performance issues	<u>Short-term</u> <ul style="list-style-type: none"> • Acute compliance & performance issues resolved • Prevention mechanisms within internal quality system installed <u>Long term</u> <ul style="list-style-type: none"> • Performance levels improved

- Which **contextual factors increase** the effectiveness of regulatory standards according to your experience?
- Which **contextual factors reduce** the effectiveness of standards?
- What is your experience with the effectiveness of prior risk assessments and data analysis HIW conducts? This question relates to the **actual implementation**.

Further, more detailed questions:

- What **differences**, if any, in the effectiveness of prior risk assessment and data analysis have you experienced? (e.g. availability of data concerning NHS and independent sector hospitals, different sources of data, collaboration with other regulators in Wales...)
- What **changes** if any would you suggest concerning the risk assessment and data analysis that the HIW conducts prior to the hospital inspections? (i.e. which aspects could still be improved by HIW, which are already perfectly suiting?)

2.3 Type of inspections

I would like to go with you through the specific mechanisms and effects that the different types of inspections have, such as announced, unannounced, themed inspections.

But before looking at these types of inspections, I have 2 clarification questions.

- HOW are you going to 'test cultures' - The last HIW operational plan states: 'During our inspections we will enhance our review of management and leadership to test cultures in services and organisations and to review how NHS...'
- Pilot infection prevention inspections (page 13 of the current operational plan).

2.3.1 Let us look at **announced inspections**:

My understanding is that announced inspections in hospitals are only conducted during follow-up visits or thematic reviews (i.e. in one particular area). – Is this correct?

- According to your experience, what is the **particular mechanism** that makes announced visits work?
- Which **contextual factors increase** their effectiveness according to your experience?
- Which **contextual factors reduce** their effectiveness?

Possibly, check the following scheme with Interviewee

Regulator	Regulated hospital	Possible output/outcomes
Announces date/time of its inspection in advance	<div>1. Identifies non-compliance issues and takes immediate remedy action prior to the inspection</div> <div>2. Informs and instructs staff accordingly</div> <div>3. Arranges for relevant staff and documents to be available at the inspection</div>	<u>Short-term</u> <ul style="list-style-type: none">• compliance & performance issues improved• 'evidence' on compliance & performance manipulated• hospital staff informed and prepared• disruption minimised <u>Long term</u> <ul style="list-style-type: none">• hospitals rely on schedule and make less efforts until the next announced visit

Further, more detailed questions:

- **In which cases** or for which hospitals do you recommend conducting announced inspection visits?
- What is the **advantage** of announced visits against unannounced visits?
- What is your experience with the effectiveness of announced visits that HIW conducts? This question relates to the **actual implementation**.

Further, more detailed questions:

- What **differences**, if any, in the effectiveness of announced visits have you experienced concerning NHS and independent sector hospital inspections?
- What **changes**, if any, would you suggest concerning the announced inspections that the HIW applies for hospital inspections? (i.e. which aspects could still be improved by HIW, which are already perfectly suiting?)

2.3.2 Let us look at **unannounced inspections**:

- According to your experience, what is the particular **mechanism** that makes **unannounced visits** work?
- Which **contextual factors increase** their effectiveness according to your experience?
- Which **contextual factors reduce** their effectiveness?

Possibly, check the following scheme with Interviewee

Regulator	Regulated hospital	Possible output/outcomes
Inspects hospital	1. Cooperates with inspectors and / or 2. Tries to hide weaknesses	<u>Short-term</u> <ul style="list-style-type: none">• Non-compliance & performance issues identified and/or overlooked

Further, more detailed questions:

- **In which cases** or for which hospitals do you recommend conducting unannounced inspection visits?
- What is the **advantage** of unannounced visits against announced visits?
- What is your experience with the **effectiveness of unannounced visits** that HIW conducts? This question relates to the actual implementation.

Further, more detailed questions:

- What **differences**, if any, in the effectiveness of unannounced visits have you experienced amongst different hospitals? (e.g. NHS and independent sector hospital, smaller or larger hospitals)?
- What **changes** if any would you suggest concerning the unannounced inspections that the HIW applies for hospital inspections? (i.e. which aspects could still be improved by HIW, which are already perfectly suiting?)

2.3.3 Could we briefly discuss the differences between **themed inspections** and **general inspections**?

According to the evidence on the HIW website, themed inspections play a prominent role in the inspection regime. This seems to be different from other regulators or inspectorates, including the CQC.

- Could you please provide more information and explanation about themed inspections.

Further, more detailed questions:

- In what way do **themed inspections work differently** from general inspections?
- Which **contextual factors increase** their effectiveness according to your experience?
- Which contextual factors **reduce** their effectiveness?
- What **changes** if any would you suggest concerning the themed inspections that the HIW applies for hospital inspections
- The last annual report mentions '**new approaches to the review of dignity and essential care**' – What exactly did you change and why and has that proved effective? The annual report state "these changes are already having a demonstrable impact" – I do understand this for the reporting process, but what about the other processes and inspections.
- When reading the last annual report and the operational plan it seems that HIW is not conducting as many **cleanliness inspections** as it did in previous year? Is this impression correct? If yes – why is that?

2.3.4 Could we briefly discuss **self-assessments**.

My understanding is that NHS hospitals (or hospital trusts and boards???) It is then the HIW responsibility to validate those self-assessments. Correct? –

- My understanding is that those have been introduced recently, i.e. 2 – 3 years ago? Is that correct?
- My understanding is HIW tried to introduce a similar self-assessment – validation process for independent sector hospitals, but stopped that – as it did not work? Is this correct? Can you provide me with more details?
- Can you explain a bit more the system of self-assessments?
 - How done – different or in addition to other
 - How often
 - Who
 - What role do they play?

Further, more detailed questions:

- What are the **advantages and disadvantages**?
- What are the **differences** in the application of self-assessments at NHS hospitals and independent sector hospitals?
- How are the self-assessments **revalidated**? By whom, how frequently?

Independent sector hospitals told me that they submitted self-assessments to HIW, but never received any feed-back from HIW.

- What is the **procedure at HIW of handling** self-assessments after receiving them?
- What role should self-assessments **ideally** play?

2.4 Inspectors

Another important element in the inspections are the people who conduct the inspections. Regulatory bodies like HIW and CQC seem to have different policies concerning the composition of inspection teams, mix of skills, or training for staff and external lay or peer reviewers they assign.

- According to your experience, what makes **inspection teams** working most **effectively**?
- How does the **context** that the inspections are performed in influence the effectiveness of the inspection teams or individual inspectors? –and which contextual factors would that be?

Further, more detailed questions:

- Page 16 of the last HIW annual report states ‘we developed a mixed model approach to identifying and recruiting peer reviewers’? What is new with this approach? My understanding was that HIW already used peer reviewers.
- What **skills mix** should inspection teams ideally have?
 - I am interested in learning more about the contextual factors: How would that vary concerning the different attributes of hospitals (smaller or larger hospitals; independent or NHS hospitals; excellent performing or poorly performing hospitals)?
- What about the **ideal size** of an inspection team?
 - How would that vary concerning the different **characteristics of hospitals** (smaller or larger hospitals; independent or NHS hospitals; excellent performing or poorly performing hospitals)?
- Could you please explain more about the **different roles** in the team?
 - How do the roles of an HIW inspector differ from that of an external peer reviewer or a lay reviewer (what CQC calls now ‘experts by experience’)?
 - How do these roles vary depending on the different attributes of hospitals?
- What is your experience with the **actual effectiveness** of the inspection teams that conduct hospital inspection for HIW? This question relates to the actual implementation.
 - In how far, do you think, are inspection teams able to spot critical issues at the hospitals and correctly assess hospital performance?
- What **changes** if any would you suggest to the HIW concerning individual inspectors and inspection teams? (i.e. which aspects could still be improved by HIW, which are already perfectly suiting?)

HIW Inspectors and staff

(a) HIW’s operational plan states on page 42 as one of HIW performance standards ‘to have at least 70% of HIW staff survey respondents state that they have been able to access the right learning and development opportunities when they need to’ and ‘to hold at least 8 staff seminars during 2014-15’

- ➔ Could I get access to the HIW staff survey (i.e. summary reports) that have been conducted so far? Is this the same survey that the last HIW annual report was referring to on page 27 'Each year the Welsh government undertakes a survey of all staff to assess their views on how effectively the organisation works.'?
- ➔ Could I get access to HIW's training calendar for 2014 (or what are the topics and learning objectives of the above mentioned 8 seminars?)
- ➔ Does HIW encourage their staff to develop individual personal development plans and what is the process for monitoring their implementation? –
- ➔ The last HIW annual report mentions on page 27 a 'professional skills framework' – could I see this?

(b) HIW staff: the last annual report states on page 4 'we have a staff complement of about 60', on page 27 the report lists in a table 41 permanent staff and 10 fixed term staff, which makes a total of 51, i.e. not 60.

- ➔ What is the profile of HIW staff, i.e. **how many** are senior inspectors, what is their **background** etc.
- ➔ The table on page 27 of the last HIW annual report shows 15 permanent and 2 staff members with a fix-term contract leaving HIW (since April 2013) – do you conduct conversations with leaving staff members and if what do they state the reason for their leaving?
- ➔ page 27 of the last HIW annual report mentions in this context a 'staff churn' and moving HIW head office to Merthyr Tydfil. So why did HIW move?

(c) The last HIW operational plan states: 'We will continue to listen to the voice of the patient (adult and child). We will establish a larger pool of lay reviewers who will receive enhanced support and communication from HIW staff and help us to ensure that the patients' perspective is reflected in our work.' –

- How are lay reviewers recruited? – Individuals who volunteer – or patient organisations – or??? What is the motivation of those people? Are they compensated? How often do they participate in inspections?
- Are the lay reviewers trained before they participate in the inspections? If yes, what does the training include? And for how long?

2.4 Instructions and recommendations for improvement


As far as I understand, the inspected hospital receives information about the detected non-compliance issues firstly **orally** during and at the end of the inspection and secondly and more profoundly in the **report** afterwards. Is my understanding correct? If not, please clarify.

If there are non-compliance issues, the hospital will then be required to produce an **action plan** to tackle these issues. Correct? The hospital may also receive **practical recommendations** for improvement alongside the inspection and the report. Is that correct, too?

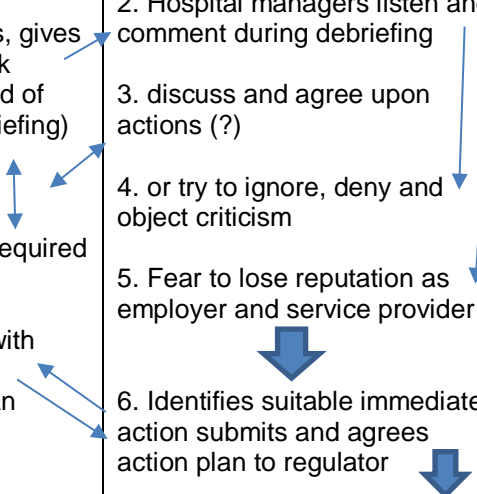


- According to your experience, what mechanisms and factors do make the **instructions and recommendations** work most effectively?
- How does the **context** the inspections are performed in influence the effectiveness? –

- and which **contextual factors** would that be? (smaller or larger hospitals; independent or NHS hospitals; excellent performing or poorly performing hospitals)

Possibly, check the following scheme with Interviewee (simplified version)

Regulator	Regulated hospital	Possible output/outcomes
Provides recommendations to the regulated hospital, including actions to be taken by the hospital	 <ol style="list-style-type: none"> 1. Implements recommendations or 2. Ignores recommendations 	<u>Short-term</u> <ul style="list-style-type: none"> • Actions implemented accordingly • Performance improved • Poor performance continues <u>long-term</u> <ul style="list-style-type: none"> • Cooperation and appreciation (or not) of the regulator's role & advice

Possibly, check the following scheme with Interviewee

Regulator	Regulated hospital	Possible output/outcomes
<ol style="list-style-type: none"> 1. summarises and prioritises the issues, gives immediate feed-back during and at the end of the inspection (debriefing) and (if necessary) 2. indicate need for improvements and required (immediate) actions 2.a agrees actions with regulated hospital /approves action plan 	<ol style="list-style-type: none"> 2. Hospital managers listen and comment during debriefing 3. discuss and agree upon actions (?) 4. or try to ignore, deny and object criticism 5. Fear to lose reputation as employer and service provider 6. Identifies suitable immediate action submits and agrees action plan to regulator 7. implement changes to resolve problems 7a. take long-term actions to prevent performance problems and avoid future exposure and embarrassment  	<u>Short-term</u> <ul style="list-style-type: none"> • Action plan • Acute compliance & performance issues resolved • Prevention mechanisms within internal quality system installed <p>(or negative)</p> <ul style="list-style-type: none"> • Denial of problems, inability / incompetence of current management <u>Long term</u> <ul style="list-style-type: none"> • Performance levels improved • Or negative: Problems remain unsolved by the current hospital management

- What is your experience with instructions and recommendations that HIW provides in oral and/or written form? This question relates to the **actual implementation**.

Further, more detailed questions:

- What changes if any would you suggest concerning the risk assessment and data analysis that the HIW conducts prior to the hospital inspections? (i.e. which aspects could still be improved by HIW, which are already perfectly suiting?)

2.5 Inspection reports

Although we have partly touched the element of 'reporting' in the last section, I would like to look now more specifically at inspection reports and the mechanisms and factors that make them an effective element of the inspection regime.

- According to your experience, how do inspection reports become most effective? (working mechanisms)
- What is their particular purpose concerning Information provision
For example:
 - Information to be used by other stakeholders (users, government, commissioning bodies) in decision-making (direct or indirect influence on the provider, content, form and timescale comprehensible and usable)
 - Information to be used by providers in compliance and improvement – (audience for information provision is the provider community; providers find information useful to guide their action; willingness and capacity provided)
 - Information as a mechanism for public accountability (both the regulator itself and regulated organisations accountable to the public; publication is a purpose in itself)
- Which **contextual factors increase** their effectiveness according to your experience?
- Which **contextual factors reduce** their effectiveness?

Regulator	Regulated hospital	Possible output/outcomes
1. summarises and prioritises issues in a draft report, incorporating comments made during debriefing 2. submits draft report 4. Publishes report and press release on website (to be accessed by public, media, patients, other healthcare providers, politics)	3. Hospital managers read and correct factual mistakes 4. try to ignore, deny and object criticism 4.a takes legal actions(?) 5. Fear to lose reputation as employer and service provider 6. Conduct immediate action to resolve problems and implement changes 7. take long-term actions to prevent performance problems and avoid future exposure and embarrassment	<u>Short-term</u> <ul style="list-style-type: none"> • Acute compliance & performance issues resolved • Prevention mechanisms within internal quality system installed (or negative) • Patient rates decline • Denial of problems, inability / incompetence of current management • Increased levels of complaints and legal actions against the inspection results <u>Long term</u> <ul style="list-style-type: none"> • Performance levels improved • Or negative: Problems remain unsolved by the current hospital management

Further, more detailed questions:

- The operational plan states as one of HIW's performance standards 'to publish agreed report and action plan on HIW website within a maximum 3 months of inspection.' -> why is it important to publish an **agreed** report?
 - What **difference** if any does it make when the HIW submits the report to the hospital for **commenting before publishing**?
 - Do the different attributes of hospitals play any role in the effectiveness of reports when they are prior submitted to them before publishing?
- What difference if any does the **content of a report**, for example mainly positive, or mainly negative hospital assessments make concerning its effectiveness?
 - According to your experience, how do the **different stakeholder groups** receive and react on inspection reports? E.g. Population, media, other hospitals, NHS, or other organisations or individual
 - What impacts does a negative assessment report have for NHS hospitals?
 - What impacts does a negative assessment report have for independent sector hospitals?

I do understand that there have been a number of issues raised during the recent Welsh Assembly Committee inquiry concerning the publication and accessibility of HIW inspection reports.

- What is your experience with the inspection reports that HIW provides? This question relates to the **actual implementation**.

Further, more detailed questions:

- What changes if any would **you** suggest concerning the HIW inspection reporting? (i.e. which aspects could still be improved by HIW, which are already perfectly suiting?)

2.6 Follow-up and enforcement

The Welsh Assembly Social and Health Committee inquiry documentation also mentions issues concerning the follow-up and enforcement of action as well as the cooperation with other regulators in Wales.

- Could you please provide your view on what should be **effective mechanisms for follow-up and enforcement of actions**?!

For example:

- Informal enforcement or prospect drives compliance (verbal threatening - in advance of inspection report – sufficient for the provider to comply)
- Enforcement as incentive to drive compliance (provider considers cost of enforcement - needs to be greater than the cost of compliance for provider to comply)
- Enforcement as symbolic action to drive compliance (actual content of enforcement action is not significant, - naming and shaming.)

- Enforcement as driver for other providers to achieve compliance (enforcement action against one provider is seen as providing a lesson – and a deterrence to non-compliance – to other providers)
- Which **contextual factors increase** effectiveness of those mechanisms according to your experience? (e.g. cultural changes within NHS, political changes, small hospitals, independent sector hospital, insurance-based system)
- Which **contextual factors reduce** their effectiveness? (e.g. financial cuts, economic crisis, larger hospitals, poor leadership)

Further, more detailed questions:

- How do follow-up and enforcement actions affect the hospitals and their staff?
- How do follow-up and enforcement actions affect potential patients and their relatives?
- How should the cooperation with governmental institutions be organised to improve the effectiveness of follow-up and enforcement activities?
- What **changes** if any would you suggest concerning
 - the powers / authority the HIW should be provided with in order to effectively enforce necessary actions for improvement?
 - Which differences would there be concerning the independent sector and the NHS?
 - The actual follow-up and enforcement actions that HIW conducts? This question concerns the **actual implementation**

We have looked profoundly at a number of elements of the inspection regime.

- What other relevant elements are there that we have not spoken about yet?

4 The interviewee's professional judgement /evaluation of inspections - 5 - 10 minutes

- How do you by and large judge hospital inspections from your professional point of view?
- From your point of view, what are the major **strengths** of hospital inspections (that HIW conducts)?
- What are the major weaknesses of inspections (that HIW conducts) from your point of view?

Further, more specific questions:

- What specific disadvantages does the current inspection regime have?
Alternative: What negative 'side-effects'?
- From your point of view, what is the major purpose that hospital inspections seek to fulfil? (quality assurance, quality improvement, accountability, informing the government)

Further, more specific questions:

- How far do you think does the current HIW inspection regimes achieve these objectives? (e.g. scale between 0 – 10)

Proposed changes

- If you were asked to design and implement **a system** that that addressed these objectives (quality assurance & improvement etc.) within the healthcare sector in Wales, what would be its major components?
- If your task was to adopt the current HIW hospital inspection model/regime, which changes would you suggest?

5 Wrapping up - 5 minutes

- What do you consider the most important things that we've spoken about?
- Is there anything else that you'd like to raise?
- Do you have any questions?
- (Informing about further proceedings): I will send you the typed interview-text within the next few weeks. Feel free to clarify or add comments. Moreover, if you have time, it would be very nice if you could provide feedback on draft research report, which contains the analysis and conclusions of all interviews and research materials.
- (Snowballing): it will be crucial for this study to interview more people - also those with possibly different views - from this hospital or other relevant hospitals or organisations. Could you please share addresses of people with me that you think might be interested in being interviewed. Or forward my contact details to them.
- Thank you very much for the interview and your support!

Appendix 5 Transcription instructions

Rules applied during the transcription.

Feature	Transcription
Short breaks	...
Longer breaks
Vocal expressions like umm, eh (which indicate the interviewee's thinking or searching for words) and expressions like 'you know' are not transcribed	
Non-verbal expression like smiling, laughing,	[smiling] [laughing]
Inaudible	[inaudible]
Emphasis on specific words through slow and emphatic speech	<i>italic letters</i>
Comments like "how interesting" or "really?" or "wow!" which the interviewer made during the interviewee's speech to show that she was listening are not transcribed.	
Explanatory text that was not in the interview.	[]
Contractions like isn't, doesn't are kept	doesn't, isn't, can't, don't
Contractions like 'cause and 'till are spelt in the correct grammatical form	because, until
Not finishing a sentence or changing the thought	-

General rules:

British spelling rules are followed.

Agreement

This agreement is being concluded between Anne Christine Hanser as principal and Nazareno Bazo Ghezzi as contractor with regard to the evaluation study 'Watchdogs for healthcare'.

Both parties have agreed on the following tasks and responsibilities for

Anne Christine Hanser as principal:

- Will provide to the contractor digital recordings of selected interviews, she has taken in Wales.
- Will indicate to the contractor which parts to transcribe, in case an interview is only to be transcribed partially.
- Will provide transcription guidelines, examples and any guidance necessary for the contractor to transcribe the documents.
- Will check the quality of the transcription and remunerate the contractor in a timely manner. The basis of the payment is 100 EURO per 60 minutes digital recording (which is the length of a standard interview). Significantly shorter or longer interviews will be remunerated proportionally.

Nazareno Bazo Ghezzi as contractor:

- Will transcribe the digital recordings verbatim as complete as possible. Any words or sentences that are not identifiable will be noted as [inaudible] in the transcripts.
- Will follow the transcription guidelines, example and guidance provided by the principal.
- Will submit the transcripts to the principal in a timely manner.
- Will ensure absolute confidentiality about the content of the digital recordings, in particular the contractor will not disclose to anybody the names or roles of interviewees or people mentioned in the recordings / transcripts. He will also make sure that no third party will have access to either the transcripts or recordings. This will in particular entail the safe and password protected storage of the files on the contractor's computer. No copies of either transcripts or recordings will be kept or held on any of his equipment. Transcripts, recordings and any confidential information related to both will be permanently destroyed after the transcripts have been finally submitted to the principal and their receipt been confirmed by the principal.

Anne Christine Hanser
(signature)

10th October 2014



Nazareno Bazo Ghezzi
(signature)

10th October 2014



NAZARENO BAZO
GHEZZI

Appendix 7 Coding framework

Code - Level 1	Code - Level 2	Code - Level 3	Code - Level 4	Code - Level 5	Notes / Explanation
Context					Contextual factors which influence the development, organisation and effectiveness of HIW hospital inspection regimes
	UK and Wales				Differences and similarities between UK and Wales
		Wales = small country			The impact the small size of the country has, e.g. the healthcare community, decision makers et al. know each other well.
		Austerity			Limited funding and cuts in HIW's and NHS budgets in Wales and beyond
		Difficult times for NHS			The increasing expectations towards the NHS in times of restricted funding.
		Welsh government & Health and social care committee			The Welsh assembly government, the Welsh government, the Health and Social Care Committee, their oversight on HIW, differences in policies (in comparison to England)
		NHS structure in Wales (and England)			The current structure of the NHS in Wales and the reorganisation in 2009. Differences between England and Wales.
	Failings in health-care				Prominent shortcomings in the UK healthcare sector, which received a lot of media attention.
		Staffordshire			
		Abertawe Bro Morgannwg			
		Stoke Mandeville			
		Tunbridge Wells			
		Betsi Cadwaladr			
	Ownership				The specific differences (and similarities) between NHS and independent health sector
		Independent health sector			
			Reputation / marketing / importance of excellence		

		Leadership/ flat hierarchy		Independent hospitals in Wales are typically smaller and have a much flatter hierarchy than the NHS structure
		Internal governance and quality management systems		
		Attitude / commitment to quality		
		Attitude towards HIW inspections		The attitude towards HIW and HIW inspections expressed by interviewees from the independent sector
		Remuneration/incentive schemes		Positive inspection results are rewarded in the remuneration / incentive schemes of independent sector
	Differences between independent sector and NHS			Interviewees pointing to the differences (size, conditions etc.) between NHS and independent sector
	NHS			
		Gaps between board and floor		The gap between the top management level of a Local Health Board and the staff delivery healthcare services. The includes decision making, information flow, access to resources.
		Internal governance and QM systems		This particularly refers to internal 'inspection' mechanisms like HIW inspections, exercised by top managers of the HCO
		Organisational culture and leadership		
		Accredited services		NHS services which underwent accreditation
		Attitude towards HIW inspections		The attitude towards HIW and HIW inspections expressed by interviewees working at the NHS
	Size and type of hospitals			
		University hospital		
		Tertiary care/cancer hospital		

		Small independent hospital		Independent sector hospitals in Wales have less than 50 beds
		General acute care hospital		
		Community hospital		Community hospitals in Wales offer a smaller spectrum of services than a general acute care hospital
		Hospice		Hospital that specialised on end of life care
		Large size		If reference was made to the large size of the organisation
	Variation in care quality			Quality of care varies across different wards within the same hospital
		Reasons for variation		Interviewees knowing or speculating what the reasons for the variation of quality of care across hospitals are
		Senior manager aware of variation		
Regulation				
	HIW's remit, purpose and general approach			
		Formal status		HIW is a governmental structure, yet claims independence
		General approach, assumptions, principles		HIW's general approach as a regulator and inspectorate, the principles it follows and assumptions it has as to how its inspections become effective
		Healthcare organisations (HCOs) adjusting		Suggestions and indications that HCOs adjust their behaviour (in response to inspection regimes)
		HIW changing and adapting		Suggestions and indications that HIW adjusts its inspection regimes (in response to changes in HCOs behaviour)
		Variety of responsibilities (too many?)		The variety of responsibilities of HIW and suggestions that those are too many for HIW to handle or cope with
		Relationship / lead review manager		Newly introduced functions in HIW to establish and maintain a relationship with a particular health board and monitor their performance
		Purpose of inspections		Overarching objective or purpose of inspections

			Quality assurance		Assuring that HCOs provide a defined (by standards) minimum of quality
			Quality improvement		Increasing the level of quality
			Informing the government		Informing the government and governmental policies
			Accountability		Making HCO (and individuals within HCOs) accountable for substandard healthcare quality
	HIW review and reorganisation				
		Capacity problems			Capacity problems arising after the changes in staff in 2013
		Size and resources			The budget and staff available to HIW
		Advisory board			
		Need for change			Need for change expressed by interviewees (or other stakeholders during review of HIW's effectiveness)
		Review into HIW effectiveness			The review into HIW's effectiveness, evidence collected during the consultation process, Ruth Marks' report
		HIW after reorganisation			HIW's situation after the reorganisation in 2014, reference made to improvements due to the reorganisation, change in staff
	Other review bodies and inspection regimes (including CQC)				
		Cooperation amongst review bodies			Formal and informal cooperation and coordination between various review bodies in Wales and beyond
			Who does what		Roles and functions of different review bodies, including the question of social care, which overlaps with healthcare
			Formal cooperation mechanisms		Formal agreements such as the concordat
			Informal relationship		Informal cooperation, also at individual level
			Coordination of inspections		Coordination or more often the perceived or acknowledged lack of coordination of inspections amongst review bodies in Wales
			Health summits		Healthcare summits are organised by HIW: review bodies from Wales meet and exchange information about HCO

			Joint inspections		Joint inspections between HIW and other review bodies in Wales
		CQC			The Care Quality Commission in England
		Trusted to care spot checks			Trusted to care spot checks were an inspection programme run by the Welsh Government, independent from HIW, but relying on HIW's peer reviewers
		Cancer peer review			Cancer peer review is an independent peer review scheme, initially supported by HIW
		CHC			Community Health Councils organise inspections in hospitals, often focusing on the environment
		CSSIW			Care and Social Services Inspectorate Wales
		Welsh Risk Pool			The Welsh risk pool supported HCOs in Wales in managing and reducing risks
Pre-inspecti					
	Health care standards				
		Developing and reviewing standards			
			Participative / transparent development process		Invitation and participation of healthcare managers / professionals in the process of developing and reviewing healthcare standards.
			Understanding what the standards aim at		Quote by representatives of independent sector, expressing why they willingly complied with standards
		Criteria for standards			
			Evidence based		Requirement that standards need to be based on (clinical, medical) evidence or at least best practice
			Generic		Generic, i.e. not very specific standards. Vaguely formulated.
			Specific		Specific to healthcare setting or healthcare service
			Measurable		Quantifiable, entails the possibility to compare the achievement of standard
			Focus on outcome (versus input or process)		Claim that standards - and thus inspections - should focus on the outcomes of healthcare rather than on inputs or the process of how care is provided

			Minimum standards		Minimum standards aim to ensure that a defined minimum level of healthcare is provided, not less.
		Doing well - doing better standards			Name of the document, published in 2010 which lists the healthcare standards for the NHS in Wales
		Independent sector standards			similar standards to the Doing well - doing better were issued about the same time for the independent sector in Wales
		Fundamental of care standards			A set of standards which are used in nursing care
		Health and Social care standards			New set of standards, issued in 2015, relating to NHS and independent sector
		Interpretation of standards			The way different people, healthcare managers / professionals, HIW reviewer interpret the standards
			Unrealistic/idealistic		Accusation that HIW reviewers interpret the standards too ambiguously
	Registration				
		Regulatory relationship			Suggestions and indications that a regulatory relationship has been formed between HIW and the regulated/inspected HCO managers
		Independent sector			Only independent sector HCO are subject of registration in Wales
		Why not NHS?			Question raised by interviewees: why NHS Organisations are not subject to registration in Wales
	Self-assessments				
		Practice of self-assessment at HCO			How HCOs in Wales organise and perform the self-assessments
			Variability		The variability in format, content and organisation of self-assessments across the different HCOs in Wales
			Im/maturity of Health board		Suggestions and indications that certain HCOs are not mature enough for an effective use of self-assessments as part of quality management / governance systems
			Too ambiguous / HIW overwhelmed		Suggestions and indications that HIW was overwhelmed by the amount of work related to validating the self-assessments

		Feeding the beast' (not purposeful)		Quote by several interviewees suggesting that the self-assessment is a formal exercise only, which entails a lot of work at HCOs, but does not necessarily achieve its purpose
		Feedback on Self-assessments		The feedback / response that HCOs receive upon the submitted self-assessments
			Perceived lack of feedback	
		External validation (needed)		The need for external validation of self-assessments expressed by several interviewees, some referring to 'not letting turkeys voting for Christmas'
		Benchmarking and league tables		References made to the possibility / missed opportunity of benchmarking and league tables
	Selection of inspection sites and pre-inspection information			
		Analytical capacity		The capability of HIW (and thus HIW's capacity) staff to analyse data prior to inspections and thus select purposefully inspection sites
			HIW staff expertise	Professional background, experience, expertise of HIW in analysing data
			Data sets	Defining the 'right' set of indicators to predict substandard quality and thus to purposefully select inspection sites
		Access to data		HIW's ability to get access to relevant healthcare data
			Ward-specific information	Quantitative and qualitative data which help to identify underperforming hospital wards and thus to purposefully select inspection sites
			Sources of information	such as complaints from patients, information received from whistle blowers, other review bodies etc.
		Number of wards		Number of inspection sites
			Number of wards per inspection	How many hospital wards or departments were inspected during one inspection
			Suggested ideal number	Suggestions or indications as to what would be the 'ideal' number of sites to be inspected during one inspection

Onsite Inspection			Multiple hospital sites		If during one inspection two or more different hospitals of the same Health Board were inspected (occurred during new scheme in 2015)
	Selection of hospital and wards				How inspection sites (hospitals, wards and departments) are selected.
		Presumed by HCO as based on intelligence			Interviewees from HCOs assumed that HIWs selection of inspected sites (hospital wards or departments) was informed by 'Intelligence'
		No idea why ward was chosen (HCO)			Interviewees from HCOs stated that they did not know on which basis HIW had selected the ward/department, nor did they assume that there was any particular reason
		Deviated from initial choice (because of MRSA etc.)			The (rare) cases where HIW choose not to inspect a ward it had initially selected. Typically, this was due to a reason and HCO interviewees appreciated the decision as appropriate
		Not disclosed to peer reviewers until day before			Information about the hospital to be inspected is not disclosed to the peer reviewed until the day before. This is to prevent leaks.
	Assessment/judgement				Suggestions or indications as to how (statistical) data and other information about an inspection site informs the assessment in general and the judgement of reviewers in particular
		Data is not all - seeing it with my own eyes			Quote by a reviewer, referring to the necessity to visit the hospital and not rely on data only
		Piecing things together', synthesis			Referring to the amount of information which needs to be synthesised in order to make a final judgement
		Not wanting to know prior to inspection			Some reviewers refusing to see the data before the inspection, thus to avoid 'framing' (positive or negative pre-assumptions about the site)
	Inspection themes and topics				Themes and topics that determine the content of the inspection, i.e. which standards an inspection inspects against
		Comprehensive compliance (during the 2000s)			HIW comprehensive inspection regimes that was run in the early years

		Cleanliness and Infection control		HIW's programme in the late 2000s and early 2010s, including Cleanliness spot checks
		DECI		Dignity and Essential Care inspections - HIW main inspection programme for hospitals
		New inspection regime (2015)		A hospital inspection regime, HIW introduced in 2015, like DECI, but inspecting against a wider range of standards and including multiple sites
		Independent sector regimes		HIW's inspection regimes for independent sector hospitals, inspecting against a large range of standards
		Special and thematic reviews		Special reviews or review programmes which focus on a particular issue, often across HCO in Wales
		Proposals for future schemes and topics		Proposals made by interviewees as to future inspection schemes, themes or topics
	Frequency, timing and duration			Any issues related to when, how often, how long and thus how thorough the inspection was conducted
		Frequency		
			Not enough HIW inspections	Suggestions and indications that HIW inspections were not frequent enough. This relates to HCOs which had not been inspected by HIW for several years.
			Too many inspections	Perception of interviewees that their HCOs were 'over-inspected', 'inspected to death'. This does not necessarily relate to HIWs inspection only. Sometimes, interviewees referred to poor coordination of inspections amongst review bodies
		Timing		Day of the week or time of the day, when inspections take place
			out of hour inspection	Inspections that are conducted during the evening or night or during the weekend.
		Duration		How long the inspection lasts
			One day	
			Two days	

			Perceived as 'snapshot'		Perception that the inspection only reflects one moment in time and therefore is not necessarily 'representative'	
		Thoroughness			How thorough the interviewees perceived the inspection to be conducted	
	Inspection mode				Whether the inspection was announced in advanced to the HCO or the inspection team occurred unannounced at the hospital	
		Unannounced				
			Purpose / reason / advantages / disadvantage		Rationale, benefits and potential disadvantages which interviewees associated with the unannounced mode of inspection	
			Interviewee preference		Preference which interviewees expressed for unannounced mode	
		Distinction between unannounced and announced			The difficulty to distinguish between unannounced and announced inspections	
			Call to CEO 30 minutes before		Statement made by an interviewee that HIW calls the CEO of the HCO 30 minutes prior to the inspection	
			Second day of unannounced inspection		The fact that the second day of a two-day inspection is no surprise anymore for the HCO	
			Could arrive any day		The expectation by HCO managers that an inspection is likely to arrive	
		Announced				
			Purpose / reason / advantages / disadvantage		Rationale, benefits and potential disadvantages which interviewees associated with the announce mode of inspection	
			Interviewee preference		Preference which interviewees expressed for announced mode	
		Invited inspections			HIW inspections that were triggered by the request of a top HCO manager	
		Inspection methods, process and tools				How the inspection is conducted on site
			Process			Sequence of activities and how the process was conducted / perceived
				Consistency		In how far the inspection was perceived to be conducted in a consistent manner, with as little variation in the application of methods

	Methods			Data collection / assessment methods applied during the onsite inspection
		Document review		incl. Patient records, statistical data reports, internal audit reports, fundamental of care reports
		Interviews		
			Patients & relatives	
			Staff	Which staff is interviewed, how far are non-nurses been interviewed, Staff pointing to shortcomings
			Senior managers	Are managers and especially senior managers been interviewed - or not. Why not?
			'interception' by senior manager	HCO managers try to 'intercept' HIW reviewers to highlight / share specific information
		Surveys		for staff and patients/relatives
		Observation		Which areas are being observed?
		Smell		Interviewees (particularly reviewers) referring to the importance of using 'all sense', including their noses
		Intuition and experience		Interviewees (particularly reviewers) referring to intuition and experience
	Tools			Tools (such as checklists) which HIW uses during the inspection
		Structure and flexibility		Interviewees (particularly reviewers) referring to the balance between the structure (of a tool) and the flexibility for the reviewer to apply the tool and make an informed judgement
		Access to inspection tools		Whether the inspection tools are available to the public or particular stakeholders
			Public	Publicly available inspection tools
			Managers do not know	Interviewed HCO managers state that they do not know the tools HIW uses
			Managers know	Managers (seem to) know HIW tools, typically through the peer reviewers
		Questionnaires/ checklists (HIW)		

	Inspection team	Prompt card		Prompt card used by Trusted to care spot checks
		Team		
		Roles, teamwork		How the different members of the team cooperate with each other as a team
		Team composition		This includes the mix of competencies and professions within the inspection team
		Team size		This includes the question what the ideal number of reviewers is, whether there were too many or not enough reviewers in the inspection team
		No physicians		Interviewees stated that the inspection team did not include a physician
		Unclear professional background		Interviewed HCO managers were uninformed about the professional background of the reviewers
		Inspection lead		Usually a permanent HIW employee who leads the inspection team
		Characteristics		What were or should be the characteristics of the inspection manager
		Leadership role		How, whether the inspection manager performed the leadership role
		HIW peer reviewers		The clinical / professional reviewers that HIW assigns from outside HIW to complement the inspection team
		Clinical/professional expertise		The clinical / professional expertise of these reviewers
		Double role		the double role of peer reviewers as HIW reviewer and their role within their HCO
		Outdated, lack of experience		Statements made by interviewees that a peer reviewer's expertise was outdated and therefore the inspection seen as less credible
		Lay reviewers		The non-professional reviewers that HIW assigns from outside HIW as representatives of the patients and population to complement the inspection team
		Attitude and behaviour		Attitude and behaviour of members of the inspection team that interviewees referred to

Post-inspection			Interpretation / judgement		How data and findings are interpreted, and judgement is formed
			Balance: friendliness and rigour		The balance between communicating in a friendly way, but at the same time applying rigour - which interviewees referred to
		Training, induction, review meetings			Meetings, induction and training of reviewers organised by the regulator
	Oral feedback				Feedback given to the HCO during and at the end of the inspection (debriefing)
		Interaction with participants			Interaction between the inspection team and participants of the debriefing
			Who presents feedback		Who does and who should present the inspection finding to the audience
			Composition of audience		Which HCO professionals and managers attend the meeting, should attend the meeting, and what does this reflect
			Two-way communication / reaction on feedback		HCO manager reacting to feedback given by the inspection team
			Emotions		Emotions that arise during the meeting, the difficulty of managing emotions
		Type and content of feedback			
			Perceived credibility		How interviewees perceived the feedback in terms of credibility. Did they perceive it as substantiated?
			Fair and balanced content		Whether interviewees perceived the feedback as fair and balanced, i.e. it included a fair proportion of positive and negative findings
			Focus on negative aspects		Whether interviewees perceived the feedback as too negative
			Inaccurate or not contextualised information		Whether interviewees perceived the findings as inaccurate or not contextualised

			Feedback perceived as realistic, useful, constructive		Whether interviewees perceived the recommendations or proposed actions as realistic, useful and constructive	
		Discrepancies (between debriefing and reports)			Any discrepancies that interviewees noticed between the feedback and the later inspection report	
			Oral feedback more positive than the report			
		Recording feedback (including recommendations)			Whether and why interviewees made notes during inspections and or debriefing	
			Making notes during inspection			
			Actively seeking advice		HCO manager are actively seeking advice from the inspection team	
			Making notes during debriefing			
		Immediate action				Suggestions and indication that immediate action was required and or implemented after the inspection
			Management letters			Management letters or assurance letters which HIW issues to HCOs
				No letter = positive result		The absence of a management/assurance letter is considered as a sign that the inspection findings were rather positive. Vice versa is the number of management letters received by a Local Health Board considered an indicator of poor performance
		Acting upon advice /issues immediately (HCO)			Suggestions and indication that the HCO took immediate corrective actions	
		Reporting and publication			The preparation and publication of inspection reports, including the submission of draft reports to the HCO for accuracy check	
			Process and targets			How the reporting process is organised and HIW time targets
		At HIW			The reporting process and targets at HIWs side	

		At the healthcare organisation		The receipt of the draft report at the HCO and how it is processed internally
Target group and mechanisms				at which audience are the inspection reports targeted and which mechanisms are presumed
		Reading and readability		Who reads the reports, do style and language support readability
		Traffic lights, scores (reducing complexity)		
		Format, structure		
		Government reading reports		
Findings and recommendations				
		Findings substantiated		Interviewees perceive the findings as substantiated and justified - or not
		Recommendations perceived as good advice		Interviewees perceive the recommendations as 'good advice'
		Recommendations perceived as unrealistic		Interviewees perceive the recommendations as unrealistic
		Unidentified shortcomings		HIW failed to identify / report a non-compliance issue / shortcoming at the hospital
		Many, detailed recommendations		
Accuracy and QA				How does HIW make sure that the reports are accurate
		Role of peer reviewers		The role of peer reviewers in the reporting process
Delays in reporting				Delays in publishing the inspection reports on HIWs website
		Causes of delays		What have been the (presumed) causes of the delays
		Impact of delays		What (potential or real) impact did the delayed reports have
Publication and reputation				
		HIW Website		Perceived user-friendliness or unfriendliness of HIW website
		(perceived) Positive reports		What are the reaction of HCO professionals and managers concerning inspection reports that they consider as positive for them or their reputation

		(perceived) negative reports		What are the reaction of HCO professionals and managers concerning inspection reports that they consider as negative for them or their reputation		
		Sharing good practice		How good practice examples - mentioned in inspection reports - are shared across different HCOs		
		Photographs		Role of photographs published in Cleanliness reports		
		HIW visibility in the media		How far is HIW visible in the media and thus create the impression that an inspection is likely any time (-> alerts hospitals)		
		Media focus on negative findings		Interviewees referring to the general focus on negative news in the media. I.e. positive inspection findings do not make it into the news		
	Action plans					
		How and who develops			How and who within the HCO coordinates and develops the action plan	
			Consenting internally		the process how action plans are consented inside the HCO	
			Too many (fragmentation), losing sight		Interviewees referring to too many action plans, instead of an integrated plan and that the action plan alone does not mean implementation	
		When developed			When the HCO starts developing the action plan	
			after onsite inspection			
			after receipt of inspection report			
		Meaningful action plans			Interviewees referring to the quality or poor quality of action plans	
		Implementation			Interviewees referring to the implementation of action plans and factors which might impede implementation	
		Publication of action plans (HIW website)			Action plans should be published alongside the inspection reports, but are not always	
		Follow-up				
			Whose role is follow up?			
			Follow up by HIW			
				No follow up by HIW		

		so called 'Follow up'		Follow up inspections in 2014 - due to lost reports/HIW reorganisation
		Unannounced or announced		Whether follow-up inspections were announced or unannounced and whether this makes a difference
		Part of next routine inspection		Embedding follow up into the subsequent routine inspection
		Internal monitoring by healthcare organisations		How HCOs monitor implementation of action plans and interact with HIW
	Enforce ment			
		Enforcement powers	The formal enforcement powers that HIW has	
			Difference NHS - independent sector	HIW's enforcement role in the independent sector compared to its power over NHS
			Examples	Cases where HIW used its enforcement powers
			More enforcement necessary?	The question interviews raised or answered as to whether HIW needs to have more enforcement power and or execute more enforcement
		Informal mechanisms	Any informal mechanisms HIW uses to make HCO implement corrective actions etc.	
			Examples	Cases where HIW used informal mechanisms
		Informing the government / escalating	The formal and informal process of informing the government and escalating	
			Tripartite meetings	Tripartite meetings between HIW, the Welsh Government and the Welsh Audit Office as part of the escalation process
	Impact			
		Leverage (inside the HCO)	HIWs inspections and inspection reports helped to sway the decision / argument	
			For a particular stakeholder group	HIWs inspections and inspection reports were used to convince or persuade a particular stakeholder group
			HIW findings = impartial evidence	HIW findings were valued because they were considered as impartial evidence
			Additional weight	HIW findings were valued as they were adding weight to an existing cause

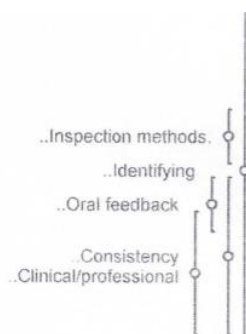
	Tried before, but not successful		Cases where interviewees had tried to improve the situation, but were unsuccessful - before HIW inspection
	Reallocation of funds, change in priorities		HIW's inspection report led to a change in the priorities of actions and reallocation of funds (towards the implementation of the recommendations)
Examples of effectiveness/ changes			
	Mental healthcare inspections		Reference was made to HIW's mental healthcare inspection regime
	Infrastructure/e nvironment		this includes improvement of furniture, sanitation, floors, walls, curtains, hearing loops
	Behaviour changes		This includes changes for exchange hand hygiene, communication with patients
	Service improvement		This includes improvement of patient experience, clinical effectiveness etc.
Factors that undermine effectiveness			
	Lack of financial resources		Lack of financial resources or not sufficient value for money associated with the investment
	Leadership issues, organisational culture		Interviewees referred to a lack of leadership or the organisational culture which was not conducive for change
	Reluctance to accept and act upon negative findings		Interviewees seemed reluctant to accept the findings and recommendations for corrective actions because considered the findings as not based on evidence and best practice criteria, or they considered them as not significant and not systemic.
	Perceived lack of power to effect change		Interviewees feel that they lack the power/authority to effect change
Frontline hospital staff			What impact HIW inspections have on frontline hospital staff
	Become more familiar, less frightened		Being frequently exposed to inspections makes staff less frightened
	Intimidated / frustrated / desensitised		Frequent inspections intimidate staff and frequent, negative inspection results frustrate and desensitise them
	Understanding the rationale, positive attitude		When frontline staff is explained the rationale of inspections, they understand the importance and develop a positive attitude

	Preparation, moral support by senior managers		Senior managers try to prepare frontline staff for an inspection and provide moral support during the inspection
Identifying non-compliance issues			HIW inspections identify non-compliance issues
	Known to senior manager but not acted upon		Senior managers have been aware of the shortcomings before HIW identified the issue, but have not acted upon
	Known to senior manager - action started		Senior managers have been aware of the shortcomings before HIW identified the issue and initiated action. But the action is not completed yet.
	Not known to senior managers		
	Quality committee identifies across reports		The HCO quality committee reviews HIW inspection reports and identifies systemic issues
Comparison with other healthcare organisations			HCOs read inspection reports of other HCOs, learn and improve
	Learning from negative inspection findings		HCO try to avoid making the same mistakes (preventative effect)
	Learning from positive inspection findings		Learning from best practice of other HCOs
Disturbance during inspection			Inspections disrupt the care process at the inspected hospital ward / department
	Less time for patients during inspection		HCO staff have less time for the patients
	(Potentially) causing mistakes / medical errors		The disruption causes mistakes / medical errors
Patients' and relatives' reaction			Impact that HIWs inspection reports have on patients and relatives
	Decision influenced by positive (or negative) findings		Patients and relatives take informed decisions as to which hospital to choose based on HIWs findings (inspection reports)
	No choice anyway		Patients and relatives in the NHS in Wales have no choice of hospital

			Patients (temporarily) unsettled		NHS patients are temporarily unsettled
		Government actions			The Welsh government takes appropriate actions based on HIW's findings
		Recommendat ions for changes			Recommendations that interviewees make concerning changes in HIWs inspection regime and or the quality management / governance systems Wales

Appendix 8 Example of coded interview transcript

<p>..Frequency, timing & ..Thoroughness</p>	<p>83 ACH: So, how does the new format differ from the old format?</p> <p>84 IN: I think they are only spending ... a more limited time within the area. They said they weren't able to go through all of the documentation, and it would be more superficial, whereas and they described, I remember [name] describing the other reviews as peeling an onion. You would peel off the layers to get down to the core, whereas now it was just a sort of overview of events. However, where they did have concerns, because they did have concerns about something in one of my areas, they did go back</p>
<p>..2 days</p>	<p>85 ACH: I am just a bit surprised that you mention that [name] mentioned that it was less thorough or more superficial, because -</p> <p>86 IN: [information that could lead to the identification of the interviewee].</p> <p>87 ACH: But, previously they spent only one day, and now they came for two days.</p> <p>88 IN: No, no, this time- well... no, they were two days [year] as well.</p> <p>89 ACH: Ok, but I saw many reports of HIW were they only spend one day, so...</p>
<p>..2 days ..Multiple hospital sites</p> <p>..Identifying noncompliance</p>	<p>90 IN: When they came to [type of department or ward], they also came to [type of department or ward], and for example, in [hospital] they did [types of departments or wards] all in two days.</p> <p>91 ACH: I see. They had more areas to inspect.</p> <p>92 IN: Yes, yes.</p> <p>93 ACH: What do you prefer, from your perspective? Would you prefer more intensively into maybe one or only two, or a bit more superficial?</p> <p>94 IN: It is difficult to say, because it has its advantages. And, as a manager, really it is nice to have that new pair of eyes. But, really speaking, most of us actually know what the issues are within our areas, and we are working hard to address them. So, what they normally identify shouldn't be a huge surprise to us, I don't think.</p>
<p>..Immediate action ..Attitude towards HIW</p> <p>..Acted upon advice/issues ..Examples of</p>	<p>95 ACH: So, there was nothing that they brought up during the feedback or in the reports, that-</p> <p>96 IN: Well, we had to- on the first day immediate action, which I think is good, they tell you that if there is anything immediately. And for us back in [month], it was [case], not every patient has [case-related], so we had to-as a health board, [information that could lead to the identification of the interviewee]. And we turned that around quite quickly.</p> <p>97 ACH: Were you aware of this problem before HIW mentioned it?</p>



98 IN: We were looking at- we had had the odd problem with [related to case], but we were looking at putting it as part of our core metrics anyway, in relation to a checking mechanism... And that is the other thing. I didn't get the impression they were auditing exactly the same things across the sites. But that may have been, you know... it didn't feel- the feedback was slightly different, and I suppose that is due to individual strengths and weaknesses of the reviewers and whether they have knowledge of the areas. Because I went to [number of] feedback sessions I was able to see the differences.

99 ACH: And you said it is probably more connected to the individuals. And you said about the size of the inspection teams. How many people were there? Which profiles did they have?

100 IN: There was a lay and...

101 ACH: A lay, for each ?

..Inspection team

102 IN: .. Yes, I think there was. I was at [inaudible], it was a lay. And I think there was three of them in each site.

103 ACH: So, it would be one inspector from HIW, and a peer reviewer,

..Inspection team

104 IN: Yes, and ... it's difficult, because [name] was part of the team in [hospital], and there was another two people

105 ACH: Did they introduce themselves? Would you know who they are, which profiles? Whether HIW or-

106 IN: Yes, normally they do come that morning and introduce themselves. ... We did not know they were coming at all, I had a phone call first from one of the nurses on one of the sites, to say HIW turned up. And within minutes the other nurse called from another site. So it was quite good.

107 ACH: I have heard sometimes in the past, the lead inspector of HIW would phone the executive director of the health board before entering. But I have not heard that recently. Do you know?

108 IN: I think it did happen that morning, but I think it happened within minutes of them arriving. I think it was shortly before.

109 ACH: So, it's not only that your manager in the hospital informs you, but also HIW informs you?

..Distinction between
..Oral feedback

110 IN: Yes, and it's the same with any visit, whether it is CHC or HIW, they will automatically alert us, in case- because of the feedback sessions, and-

111 ACH: Yes, of course. What about their ability to identify critical areas, that maybe you were aware of and maybe they didn't identify?

..Methods
Identifying noncompliance



..Known to senior
..Infrastructure/environment



..Identifying noncompliance
..Not known to managers



..Action plans
..Infrastructure/enviro
..Additional weight
..Leverage (inside HCO)



..Additional weight
..Relocation of funds, change



112 IN:

113 ACH: Were you surprised that something was not mentioned that you thought-

114 IN: I am trying to think of the recent.

115 ACH: Well, not necessarily the recent, but during the year-

116 IN: I can't think of anything. The ones we had, they picked up things. I don't know, going back, if there was more- I think more recently there is more emphasis, but they were in [type of] care asking about staffing levels, which I thought was very good that they were asking about the staffing, because that does have a huge impact in our quality of care delivery.

117 ACH: You said, principally there shouldn't be a surprise when HIW tells you what they found.

118 IN: Generally, we know. For example, if they picked up anything about the environment, it's normally on our plan in paper that we wanted the environment to be... refurbished. They, you know, always pick up about the complex paperwork for nursing, and how- we understand what that's like... I am trying to think... What they did pick up one thing, which I had not picked up, but they were not sure- there was an issue in one area, for example,- they were concerned [information that could lead to the identification of the interviewee], to see if any of their concerns were founded - or was it just something in the moment of time that things were not best. I thought that was really good, and that they then fed that back to us. So, no, I don't think there is much that they have found that we weren't aware of.

119 ACH: So, where is then the added value from your point of view of HIW's inspections?

120 IN: I think it is always useful to have an action plan, because the action plan does sometimes support what we want done in the health board. For example, if HIW come in and they are very critical of an environment of care, for refurbishment, that gives us a huge advantage to have it upgraded.

121 ACH: But, you could do it yourselves as a health board.

122 IN: Yes.[laughs]

123 ACH: So, is it the internal mechanisms inside the health boards?

124 IN: Yes, the competing priorities. If you have something from HIW, it certainly adds weight to get things done, to get things done in a sort of probably quicker way. And I think it's very reflective when you have the action plans-